****

**TED Seed Project and Exploratory Seed Project Awards**

**Full Application Instructions and Procedure**

**FULL APPLICATIONS DUE 5:00 PM PST | Friday, October 2, 2015**

**Submit in a single pdf via email to** **Brian Fabian**

Full applications must be prepared using the enclosed forms styled after the PHS 398 in this order (Arial 11 pt, 0.5” margins; continuation pages marked with PI name and numbered consecutively):

1. Page 1 - Face Page.
2. Page 2 - Detailed Budget for Initial Project Period ($275,000 inclusive of indirect costs for Seed Projects OR $150,000 inclusive of indirect costs for Exploratory Seed Projects)
	* Maximum allowable indirect cost rate is 26%
	* Travel is not allowed
	* Purchase of equipment is not permitted
3. Page 3 - Continuation Page for Budget Justification
4. Page 4 PHS 398-style Format Biosketch for PI and any other key personnel
5. Specific Aims (1 page)
6. Research Strategy (6-page limit including figures and tables) Please be guided by Review Criteria below, and if not using TED Metadataset, provide a description of the dataset(s) that will be utilized. FDA context of use (COU) and concept of interest (COI) must be specified.
7. Milestone Graphic (1 page, not included toward 6-page limit of Research Strategy section)
8. Literature Cited (1 page, not included toward 6-page limit of Research Strategy section)
9. Human Subjects (narrative per NIH format)
10. Documentation of IRB or IACUC approval
11. Letter of Support from TED Investigator Sponsor

**Review Criteria for Full Applications**

Proposals will be reviewed based on their relevance to TED’s overall goal of developing clinically meaningful Clinical Outcome Assessments and biomarkers. The scope of work must be realistic to complete in a one-year time frame. Proposals will be reviewed using the NIH scoring system (1-9) on the criteria below:

* Overall Appropriateness - Does the proposal promote or assess the regulatory readiness of one or more clinical outcome assessments (COAs), fluid-based biomarkers, or neuroimaging biomarkers that may be used as tools for TBI clinical trials?
* Significance - How relevant are the specified COAs or biomarkers for TBI clinical trials?  Are the context(s) of use specified?  How relevant are the specified COUs for TBI clinical trials? For COA process measures: How relevant are the proposed processes to vet the strength of outcome measures, as opposed to the measures themselves?
* Approach - How relevant are the proposed methods for translation to FDA advancement? Does the proposed study address validity? Reliability? Sensitivity? Specificity? Repeatability? Is there replication? What datasets are available for use in establishing these attributes?
* Results - Does the study design permit immediate results to be generated? How will success be measured in the 1-year timeframe? Is it realistic to complete in 1 year and on budget?

NOTE: proposals that integrate the use of the new CDISC TBI clinical data standards will receive positive or preferential priority.

**Intellectual Property Documents Governing all TED Research Projects**

Before funding is released, all Principal Investigators are required to accept and execute the TED Data Use Agreement(s), the TED Publication and Authorship Guideline, and the TED Research Collaboration Agreement. These documents may be reviewed on the [TED website](https://tbiendpoints.ucsf.edu/researchers). Successful awardees will be contacted regarding execution of these governing documents.

**Quarterly Progress Reports**

Each recipient of a Seed Project will be required to submit four quarterly progress reports due on the 15th of each month following the end of the quarter. The final report will serve as the Q4 and cumulative final report. Progress reports will follow a supplied template and will include accomplishments, reportable outcomes, future plans, problems/issues, and financial compliance.

|  |  |
| --- | --- |
| Grant ApplicationDo not exceed character length restrictions indicated. | **LEAVE BLANK—FOR INTERNAL USE ONLY**. |
| Type | Activity | Number |
| Review Group | Seed project? Y N  |
|  | Date Received |
| 1. TITLE OF PROJECT *(Do not exceed 81 characters, including spaces and punctuation.)*      |
| **3. PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR** |  |
| 3a. NAME (Last, first, middle) | 3b. DEGREE(S) | 3h.  |
|       |       |       |       |       |
| 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 |       |
| 5. DATES OF PROPOSED PERIOD OF  SUPPORT *(month, day, year—MM/DD/YY)* | 6. COSTS REQUESTED FOR INITIAL BUDGET PERIOD | 7. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT |
| From | Through | 7a. Direct Costs ($) | 7b. Total Costs ($) | 8a. Direct Costs ($) | 8b. Total Costs ($) |
|       |       |       |       |       |       |
| 9. APPLICANT ORGANIZATION | 10. TYPE OF ORGANIZATION |
| Name |       | Public: **→** [ ]  Federal [ ]  State [ ]  Local |
| Address |       | Private: **→** [ ]  Private Nonprofit |
| For-profit: **→** [ ]  General [ ]  Small Business  |
| 11. ENTITY IDENTIFICATION NUMBER      |
| DUNS NO. |       | Cong. District |       |
| 12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE | 13. 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 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      |
| Program Director/Principal Investigator (Last, First, Middle): |       |
|  |
| DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY | FROM | THROUGH |
|       |       |
| PERSONNEL *(Applicant organization only)* | Months Devoted to Project |  | DOLLAR AMOUNT REQUESTED *(omit cents)* |
| NAME | ROLE ONPROJECT | Cal.Mnths | Acad.Mnths | SummerMnths | INST.BASESALARY | SALARYREQUESTED | FRINGEBENEFITS | TOTAL |
|       | PD/PI |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |       |
| SUBTOTALS |       |       |       |
| SUPPLIES *(Itemize by category)*      |       |
| TRAVEL      |       |
| OTHER EXPENSES *(Itemize by category)*      |       |
| CONSORTIUM/CONTRACTUAL COSTS | DIRECT COSTS |       |
| SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)* | $ |       |
| CONSORTIUM/CONTRACTUAL COSTS | FACILITIES AND ADMINISTRATIVE COSTS |       |
| TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD  | $ |       |

BIOGRAPHICAL SKETCH

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

NAME:

POSITION TITLE:

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

| INSTITUTION AND LOCATION | DEGREE(if applicable) | Completion DateMM/YYYY | FIELD OF STUDY |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |

**NOTE: The Biographical Sketch may not exceed 5 pages. Follow the formats and instructions below.**

A. Personal Statement

Briefly describe why you are well-suited for your role in the project described in this application. The relevant factors may include aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (you may mention specific contributions to science that are not included in Section C). Also, you may identify up to four peer reviewed publications that specifically highlight your experience and qualifications for this project. If you wish to explain impediments to your past productivity, you may include a description of factors such as family care responsibilities, illness, disability, and active duty military service.

B. Positions and Honors

List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.

C. Contribution to Science

Briefly describe up to five of your most significant contributions to science. For each contribution, indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can include audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware) that are relevant to the described contribution. The description of each contribution should be no longer than one half page including figures and citations. Also provide a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography, which are maintained by the US National Library of Medicine.

D. Research Support

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