2020 BIOSTART Grant RFA

West Virginia Clinical and Translational Science Institute
West Virginia University Tissue Bank
& Edwards Comprehensive Cancer Center Tissue Procurement Program

Last day to submit the BIOSTART Interest Form
July 13, 2020 by 5PM

FULL APPLICATIONS DUE
August 10, 2020 by 5PM

CONTACT
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PART 1. OVERVIEW

Funds are available from the WVCTSI BIOSTART Grants Program to support small, well-defined projects using samples from the West Virginia University (WVU) Tissue Bank and the **Edwards Comprehensive Cancer Center Tissue Procurement Program (ECCC Tissue Bank) affiliated with Marshall University**. **Projects must lead to measured outcomes, such as critical preliminary data for a larger grant submission.**

Note: Brain tissues are not available from the WVU Tissue Bank for the present funding opportunity at this time.

ATTENTION
Applicants ***MUST*** contact Wes Kimble, MPA, Assistant Director of Clinical Research Services, and Emily Morgan, Data Services Specialist, ***PRIOR*** to application to determine tissue availability for specific research criteria. To ensure proper guidance, complete the BIOSTART Grant Interest Form and email it to, emorgan4@hsc.wvu.edu (please copy wkimble1@hsc.wvu.edu mreeves1@hsc.wvu.edu).

Full Applications submitted without prior approval will not be considered for funding.

Budget
The budget is limited to a maximum of $10,000 in total direct costs for nine (9) months. Please see Application Instructions for detailed allowable expenses. Do NOT include tissue sample processing costs as those will be covered by the funding agency.

Compliance Requirements
PIs must secure approval from their institution's biosafety office as appropriate for their project:

- Charleston Area Medical Center Institute/WVU Charleston – Please contact your department administrator
- Marshall University – Institutional Biosafety Committee
- West Virginia School of Osteopathic Medicine –Institutional Biosafety Committee
- West Virginia University – Biosafety Unit

Proof of IBC protocol submission is required at time of application for applicable projects. Final

approval must be completed within 30 days of grant award notice. No funds can be released without proper compliance documentation.

PART 2. FULL TEXT ANNOUNCEMENT

Funding Opportunity Description

This WVCTSI funding opportunity is offered in collaboration with the WVU Tissue Bank and the ECCC Tissue Bank for the purpose of promoting the use of tissue samples in clinical and translational science research. The latter is defined as the process of making discoveries in the research laboratory or in preclinical studies that will have an impact on human health and may lead to the development of studies in humans.

Applications focused on, but not limited to, specific health areas of importance to West Virginia and Appalachia at large are currently being accepted.

Award Project Period

The scope of the proposed project should determine the project period. The maximum project period is nine (9) months.

Eligibility Information

- Principal Investigator (PI) **must hold a faculty appointment** or equivalent at the time the award is announced. Appointments can be held at CAMC Institute/WVU Charleston, Marshall University, West Virginia School of Osteopathic Medicine, and West Virginia University.
- For the purposes of this RFA, these are individuals who can independently apply for federal or non-federal investigator-initiated, peer-reviewed Research Project Grants (RPG). Individuals holding postdoctoral fellowships or other positions that lack independent status are not eligible to lead pilot projects.
- Note that Marshall University faculty members must hold an appointment in either the School of Medicine or the School of Pharmacy. Other Schools and Colleges at Marshall University are NOT currently eligible.

Restrictions

- Faculty named in the WVCTSI organization (i.e. program chairs and key personnel) are restricted from serving as PI on WVCTSI pilot grants, as well as prohibited from having funds directed to their labs or programs. However, such individuals may be included on pilot grants in supportive roles such as Co-Investigators, mentors, and consultants.
- *The Project lead for Pilot projects may not concurrently have funding from other IDeA Program award mechanisms (e.g. CTR, INBRE, and COBRE).*
- **** No human subjects projects requiring the enrollment of participants or clinical trials allowed for this funding mechanism****

Application Instructions

Please complete the BIOSTART Application Template and attach documents as appropriate per instructions in Tables 1 and 2.

Format Specifications

- Font restrictions: Use a font size of 11-point or larger. Acceptable fonts include the following: Arial, Helvetica, Palatino Linotype, or Georgia. *Please use one single font throughout the document, except as needed for special characters such as Greek letters.*
- Font color: Black only. Type density, including characters and spaces, must be no more than 15 characters per inch. Type may be no more than six lines per inch.
- Page Margins: Use standard paper size (8 ½" x 11). Use at least one-half inch margins (top, bottom, left, and right) for all pages. PI's name and page numbers are permitted in the margins but not required. Do not include any information in a header or footer of the attachments.
- Page Formatting: Standard, single-column format for the text.
- Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnote: A smaller type size (9 or 10 point) but it must be in black, readily legible and follow the font typeface requirement. Color can be used in figures; however, all text must be in black, clear and legible.
- Page Limits: Although many sections of the grant application are described as separate sections, the page limits must be followed or the proposal will be returned without review. In addition, the appendix should not be used to circumvent the established page limits.

Applications must be submitted via iLab as a single PDF document by the close of business hours (5:00 pm EST) on or before the deadline date.

Note:

- **Do not** scan documents unless absolutely necessary as this results in excessively large files
- **Do not** submit a PDF Portfolio
  - Instead, please use the "Combine Files" feature in Adobe Acrobat or equivalent file management software.
  - If one of your PDF documents cannot be combined, export it and save it as a Word file first. Combine this new Word file with the rest of your application using the "Combine Files" feature.

Please follow the detailed instructions below:

- **Table 1 items are required for ALL applications.**
- **Table 2 items are required as applicable to your project.**

If you have any questions, please contact us prior to submission.

Table 1. Required Content for ALL Applications

SECTION	DESCRIPTION	CONTENT LIMIT
Face Page	Use the BIOSTART Application Template.	N/A
Project Abstract	Use the BIOSTART Application Template.	30 lines or less
Approach/Research Strategy	Use the BIOSTART Application Template. Include the sections below	2.5 pages total
	A. Specific Aims/Objectives State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology. Applicants must identify how the study objectives and outcomes are of benefit to West Virginia/Appalachian patients and communities.	½ page
	B. Research Plan Organize the Research Plan in the specified order and using the instructions provided below. Start each section with the appropriate section heading: Hypothesis, Background, Significance, Innovation, and Approach.	2 pages
	1. Background Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.	
	2. Hypothesis Clearly and briefly define the hypothesis of the project.	
	3. Significance • Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice. • Describe how the proposed project will position the PI for competitive extramural funding addressing issues significant to West Virginia and Appalachia.	
	4. Innovation • Explain how the application challenges and seeks to shift current research or clinical practice paradigms.	
	5. Approach • Describe in detail the overall strategy, methodology, sample selection and size, subject/patient enrollment, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate. • Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.	
References	Use the BIOSTART Application Template. Given the length of the application, investigators should strive to provide a relevant, although not exhaustive bibliographic review.	No limit

Budget & Budget Justification	Use the BIOSTART Application Template. For all funding cycles, the budget is limited to a **maximum of $10,000** in total direct costs with a performance period of **nine (9) months**. **Refer to the Budget section below for allowable and unallowable costs**.	No limit
NIH Biosketch	Please follow the NIH "Biosketch instructions – non-fellowship" link and use the NIH "Blank biosketch format – non-fellowship" to format each biosketch.	5 pages each
Letter of Support	A letter signed by your immediate supervisor acknowledging their support for the project and providing assurance that sufficient protected time to complete the research will be available.	No limit

Budget

General

- Personnel: Not allowed.
- Consultants: provide justification for the rate. If travel and subsistence costs are not factored into the consultant(s) cost, these should be justified separately, but still be considered a part of the total cost of the consultant(s).
- Equipment: costs equal or greater than $5,000 for a single unit purchase with a useful life of one year (or more) are not allowed.
- Materials and Supplies: provide a list of the general types of expendable materials and supplies that will, in your estimation, be required to carry out the research you are proposing. Supplies should be broken down into common categories.
- Travel: Not allowed.
- Inpatient Care Costs and Outpatient Care Costs: Not allowed. NO HUMAN SUBJECTS allowed.
- Alterations and Renovations: Not allowed.
- Publication/Documentation/Dissemination Costs: $500.00 maximum.
- Other Expenses: Not allowed.
- Computer Costs: No allowed.
- Subcontracts/Subawards: most of the justification for a subcontract should come from the sub award partner(s). **Subawards require pre-approval from WVCTSI. If you plan on using this mechanism, please contact us prior to application.**

Allowable Costs

- Funds are to be used for the conduct of the project. Note that funds cannot be used to cover any personnel costs.
- Chemistry and biological lab supplies
- Purchase of cell lines, cultures reagents, etc.
- Animal purchase and housing costs
- Specimen collection/analysis or testing

Unallowable Costs

- Salary, fringe support, or hourly pay for faculty, staff, or students, i.e. no personnel cost of any kind allowed.
- Travel costs.
- Funding will not be awarded as bridge funding for ongoing, competitive projects.
- Facilities and administrative costs, also known as indirect costs, are not permitted.

Table 2. Additional Content As Applicable

SECTION	DESCRIPTION	CONTENT LIMIT
Biosafety	• Charleston Area Medical Center Institute/WVU Charleston – Please contact your department administrator • Marshall University – Institutional Biosafety Committee • West Virginia School of Osteopathic Medicine – Institutional Biosafety Committee • West Virginia University – Biosafety Unit Proof of IBC protocol is required at time of application for applicable projects. Final approval must be completed within 30 days of grant award notice. No funds can be released without proper compliance documentation.	N/A
Vertebrate Animals	Use BIOSTART Application Template. The following headers MUST be clearly labeled: • Description of Procedures • Justifications • Minimization of Pain and Distress • Method of Euthanasia	No limit
Proof of IACUC Approval	Proof that an IACUC protocol **has been approved**. No funds can be released without proper compliance documentation.	N/A
Compliance	**For animal studies, proof of CITI Training (or its equivalent) is REQUIRED for ALL project named personnel including PIs, Co-PIs, Investigators, Collaborators, Research Assistants, Research Technicians, Lab Assistants, Lab Technicians, Students (undergraduate and graduate), and anyone actively involved in the project regardless of title.** *In rare cases, consultants who do not interact in any way with the study's design, participants, or data may be excluded.* ***Please contact WVCTSI to confirm any potential exemption.*** **Vertebrate Animals** Any course from the Animal Research curriculum groups as applicable to your project	N/A
	ATTENTION: WVCTSI does NOT have access to investigator's CITI certificates or IACUC records. Applicants MUST submit required documents.	

Review and Selection Process

Only the review criteria described below will be considered in the review process.

A. Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

B. Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each.

- Significance
- Investigator(s)
- Approach
- External Competitiveness

An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

C. Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

- Vertebrate Animals
- Biohazards
- Radiation Safety and Hazardous Materials
- Budget and Period of Support

As part of the scientific peer review, all applications:

- Will be assessed on the scientific and technical merit of the proposed project and relevance of the proposed project to outlined programmatic priorities.
- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.
- Will receive a written critique.

Final funding decisions will be made by WVCTSI and WVU Tissue Bank leadership, taking into consideration programmatic priorities and availability of funds. Appeals of initial peer review will not be accepted for applications submitted in response to this RFA.

D. Funding Priorities

The following priorities for pilot grants will be articulated to the review committee.

- Proposals with investigator teams that include clinician scientists in key roles (PI/Co-PI) with clearly articulated plans for translational application of the research. Clinician investigators must contribute an appropriate amount of effort to the project and their roles must be clearly defined in the application.
- Proposals with strong potential to secure external funding; this potential will be evaluated based on the science as well as the PI (if single PI) or the team of investigators if Co-investigators are included in the application.
- Applications in which Early Stage (ESI) and Junior Investigators propose pilot studies to obtain preliminary data for an extramural grant submission.
- Applications intended to stimulate innovation and commercialization.

Award Notices

The formal notification in the form of a Notice of Grant Award (NGA) will be provided to the applicant via email for successful applications.

Selection of an application for award is NOT an authorization to begin performance. Any costs incurred before receipt of the NGA are at the recipient's risk.

Reporting

Progress report are required to be submitted every three (3) months as per the WVCTSI calendar (July 1 to June 30). A final progress report, invention statement and the final itemized expenditures are required for closeout of an award.

PART 3. iLab INSTRUCTIONS

ATTENTION

In order to streamline and track services, WVCTSI uses **iLab**. **We ask investigators to submit requests for services though iLab in order for us to best address your specific concerns.**

To access iLab, please follow the instructions on our website.

WVCTSI continues to offer grant consultations to all of its members free of charge. If you are not already a member, you can sign up here (WVCTSI is also completely free and does not require WVU credentials).

To submit an application:

1. Log into iLab at https://wvu.corefacilities.org
2. From the home page, locate the Menu in the upper left corner by clicking on the 3 horizontal lines next to "Agilent CrossLab"
3. Click on "Core Facilities"
4. From the list of cores, select the WVCTSI Investigator Development Services.
   - Marshall and WVSOM investigators: search for WVCTSI (select "Cores are Other Institutions" next to the search box).
5. Make sure you are in the "Request Services" tab located below the West Virginia University logo
6. Scroll down to Pilot Projects Grant Submission and select "initiate request"
7. Complete the form and click Submit
8. You will be automatically redirected to your list of Requests. Make sure that it has indeed been submitted. If the request is labeled as Waiting to Submit, click on label and select submit one more time.

Note: WVCTSI values investigators from all institutions and aims to make the iLab signing up process as convenient as possible. If you experience any technical difficulties, please do contact us and we will be glad to assist you!

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.