



West Virginia Clinical and Translational Science Institute Small Grant Competition RFA (*Non-Clinical Trials only*)

ATTENTION

Small grant applications that propose the initiation of a new study meeting the definition of a clinical trial ([see NIH definition](#)) are **NOT** eligible for the WVCTCI Small grant program. Please consider our other funding opportunities for this type of project. *Note:* We recognize that in rare cases, a small grant could be used to fund a specific or add-on part of an existing clinical trial study. Such projects may qualify for our Small grant program pending special permission from WVCTSI. Please direct any inquiry to Camille Charlier, Pilot Grant Program Coordinator at ccharlie@hsc.wvu.edu **PRIOR to submitting your grant application**. Submitted proposals qualifying as clinical trials but lacking special WVCTSI approval will NOT be considered.

PART 1. OVERVIEW INFORMATION

Limited funds are available from the WVCTSI Small Grants Program to support small, well-defined projects which will lead to measured outcomes, such as critical preliminary data for a larger grant submission. Funds may be used to initiate a new project or to accelerate existing projects but are not intended for bridge support.

DEADLINES	
Spring 2019	Fall 2019
Wednesday, May 1 by 5PM	TBD

A maximum of \$5,000 per award may be used for WVCTSI services and supplies, other research supplies or services, or for research support critical to completion of the project.

Applicants are encouraged to meet with either the Investigator Development Manager (Meghan Reeves, MPH) or Pilot Grant Coordinator (Camille Charlier, MS) prior to application submission.

Please refer to the last page of this RFA for contact information and iLab directions.

PART 2. FULL TEXT ANNOUNCEMENT

Funding Opportunity Description

WVCTSI is accepting Pilot Project Funding applications for clinical and translational research focusing on, but not limited to, specific health areas of importance to West Virginia and Appalachia at large. Of note, projects with significant laboratory based components must have very clear delineation of the plan for translation of the research with impact on human health.

The National Institutes of Health (NIH) defines clinical research as: (1) patient-oriented research; (2) epidemiologic and behavioral studies; and/or (3) outcomes research and health services research. Per the NIH, translational research includes:

- 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.
- The process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans.
- Research aimed at enhancing the adoption of best practices in the community.

Cost-effectiveness of prevention and treatment strategies are also important aspects of translational science.

Award Project Period

The scope of the proposed project should determine the project period. The maximum project period is six (6) months.

Eligibility Information

- Eligible Partner Sites: Marshall University (MU), West Virginia School of Osteopathic Medicine (WVSOM), and West Virginia University (WVU) – Including Morgantown, Eastern, and Charleston Campuses. **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 for WVCTSI Pilot grants.**
- Principal Investigator (PI) must hold a faculty appointment or equivalent at the time the award is announced. 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.

Restrictions

- **The Project lead for Pilot projects may not concurrently have funding from other IDeA Program award mechanisms (e.g. INBRE, COBRE).*
- Pilot projects may not overlap with other ongoing WVCTSI-funded projects.
- 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.
- ****No clinical trials allowed for this funding mechanism.**

* **Note:** Significant prior WVCTSI, INBRE, and/or current NIH funding will likely result in low priority during the reviewing process unless the new proposal is radically different from previous projects. The WVCTSI Pilot Core Program's mission is to support the growth of investigators in order to promote high-quality research resulting in increased team science, dissemination of finding, and extramural funding success. As such, priority is typically given to promising researchers in early stages of their career and who haven't yet secured significant other funding sources. We respect the time and effort that all applicants dedicate to their proposals, and welcome inquiry about eligibility prior to any formal submission.

****Note:** We recognize that in rare cases, a small grant could be used to fund a specific or add-on part of an existing clinical trial study. Such projects may qualify for our Small grant program pending special permission from WVCTSI. Please direct any inquiry to Camille Charlier, Pilot Grant Program Coordinator at ccharlie@hsc.wvu.edu

Resubmissions

An application that has previously been submitted to WVCTSI Pilot Grants Program, but was not funded. PIs submitting a revised proposal must respond to the previous panel review summary and will have one additional page within her or his application to respond to all identified previous panel review comments. Resubmitted applications **must be received by the relevant due dates**, will be evaluated in competition with other pending applications in the appropriate area to which they are assigned, and **will be reviewed according to the same evaluation criteria as new applications**. Applications which appear to be resubmissions (regardless of the designation) are regarded as such by the program and the panel and compete on the same basis with all other applications submitted to the WVCTSI Pilot Grants Program at the same time.

Per [NIH guidelines](#), **only one (1) resubmission is allowed** for any given proposal. If you are planning on completing a resubmission, please contact the WVCTSI team prior to re-submitting your application.

Note: All documents described below require the NIH PHS 398 Forms found [here](#).

Format Specifications

- **Font restrictions:** Use a font size of 11-point or larger. The only acceptable fonts are the following: Arial, Helvetica, Palatino Linotype, or Georgia. *Please use one single font throughout the document.*
- **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. No information should appear in the margins. Specifically, do not enter the PI's name or page numbers in the margins (as was past practice with hard copy grant proposals). Do not include any information in a header or footer of the attachments.
- **Page Formatting:** Applicants are strongly encouraged to use only a standard, single-column format for the text.
- **Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnote:** You may use 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 and not considered for funding. In addition, the appendix should not be used to circumvent the established page limits.

Application Instructions

Applicants are encouraged to review the instructions provided below carefully. Applications must be submitted as a single PDF document by the close of business hours (5:00 pm EST) on or before the deadline date. **Applications MUST be submitted via the iLab website** (see instructions at the end of this RFA). The application must include the following:

1. **Face Page:** Please use the [NIH PHS 398 Face Page form \(Form Page 1\)](#).
2. **Project Abstract, Relevance, Performance Site(s), Personnel, and Stem Cells Use:** Please use the [NIH PHS 398 Project Summary and Senior/Key Personnel forms \(Form Page 2\)](#). Note that the Project Summary is limited to a maximum of 30 lines.

3. **Approach/Research Plan:** Please use the [NIH PHS 398 Continuation Page forms \(Continuation Format Page\)](#). This section is limited to 2 pages and should include the **Specific Aims/Objectives** and the **Research Plan** (including Hypothesis, Background, Significance, Innovation, and Approach sections). Please use single space text.

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.

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, Approach.

- 1) Hypothesis - Clearly and briefly define the hypothesis of the project
- 2) Background - Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- 3) Significance
 - Explain how the project is of translational significance to the health of persons in West Virginia and/or Appalachia.
 - Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice.
 - Describe how relevant concepts, methods, technologies, treatments, services, or preventative interventions will be changed if the proposed aims are achieved.
- 4) Innovation
 - Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
 - Describe any novel, theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s).
 - Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions.
- 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.

5. **References:** Please use the [NIH PHS 398 Continuation Page form\(s\) \(Continuation Format Page\)](#) to list cited literature. Given the length of the application, investigators should strive to provide a relevant, although not exhaustive bibliographic review. *Note that the References section does NOT*

count toward the 2 pages maximum of the Approach/Research Plan above, nor is it limited in length.

6. Human Subjects Protection and Vertebrate Animals.

Human Subjects:

Please download the [Human Subjects and Clinical Trials Information form](#) from the [WVCTSI website](#) and include it as part of your PDF application packet.

- **NO clinical trial allowed for this funding mechanism.** However, non-clinical trial human research projects are permitted. Please still complete the Human Subjects and Clinical Trials Information form listed above.
- For reference, information concerning NIH definitions of Human Subject research and Clinical Trials can be found [here](#).

REMINDER: This form is meant to reflect your study sample plans and expectations. Note that it does *not* constitute a formal commitment to an unchangeable sample size or demographics. We typically recommend using U.S. Census data for estimates.

Vertebrate Animals: Please use [NIH PHS 398 Continuation Page form\(s\) \(Continuation Format Page\)](#) and the [NIH Animal Welfare instructions](#) to address all appropriate bulleted items below (*no page limit*):

- Description of Procedures
- Justifications
- Minimization of Pain and Distress
- Method of Euthanasia (Note: include in the same Continuation Page, do not use the Cover Page Supplement/PHS Fellowship Supplemental form)

7. **Budget:** Please use the [NIH PHS 398 Detailed Budget form \(Form Page 4\)](#). *Note: do NOT include Form Page 5.* For all funding cycles, the budget is limited to a **maximum of \$5,000** in total direct costs with a performance period of **six (6) months**.

- **Budget Justification:** In addition to the NIH PHS 398 Detailed Budget form mentioned above, a brief budget justification section is required. Please use [NIH PHS 398 Continuation Page form\(s\) \(Continuation Format Page\)](#) to describe the following items, as needed for your particular proposal:
 - Personnel: if possible, please name co-investigators, graduate students, undergraduate students, or postdoctoral associates in your budget justification. Naming an individual in the budget justification does not represent a commitment on your part to hire that individual.
 - Equipment: equipment costs (must be equal or greater than \$5,000 single unit purchase price, useful life of one year or more) must be justified via a vendor quote for the item(s) you are requesting.
 - Travel: include a list of the names of conferences under consideration for attendance in the budget for each year of the proposal and indicate whether they are domestic or international (\$2,000.00 maximum). For field work and other research-related travel, please provide detailed information about the number of people making each trip, its duration, and other information.
 - 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.
 - Publication/Documentation/Dissemination Costs: \$1,000.00 maximum.

- **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).
- **Computer Costs:** provide vendor quote(s) or some other published source for the rate being charged to the grant. Also be prepared to justify why the computing needs could not be met using your office, department, or institutional computing resources.
- **Subcontracts/Subawards:** most of the justification for a subcontract should come from the sub award partner(s). Please refer to Section VII. Clinical and Translational Pilot Grants Program Contact to determine who you should contact if you have any additional questions regarding subcontracts/subawards.
- **Other Direct Costs:** Provide quotes, catalog prices, or other published information to justify proposed rates for other costs.

Allowable Costs

- Funds are to be used for the conduct of the project, including supplies, subject payments, assays, etc.
- Salary and fringe support for administrative assistance, students, graduate students, clinical trainees, post-doctoral and clinical fellows are permitted
- Travel funds that are needed for study conduct are allowed, if essential. Travel to collect data or for collaboration purposes can be justified separately in the budget section.
- Data analysis costs
- Research assistant salary support; applicants must account for fringe benefit costs when considering research assistant salary levels.
- Non-faculty personnel salary support
- Project specific specimen collection/analysis or testing
- Chemistry and biological lab supplies
- Purchase of cell lines, cultures reagents, etc.
- Animal purchase and housing costs
- Specimen collection/analysis or testing
- Participant reimbursement
- Publication Costs (\$1,000 maximum)
- Conference Travel (\$2,000 maximum)

Unallowable Costs

- Funds cannot be used to support salary of the PIs or other investigators with faculty appointments.
 - PIs must be listed as providing at least 10% effort concerning the project; however, this effort is not associated with salary but only with time devoted to the project as institutional commitment.
- Funding is not available for student stipends for thesis or dissertation projects.
- Funding will not be awarded as bridge funding for ongoing, competitive projects.
- Facilities and administrative costs, also known as indirect costs, are not permitted.

- 8. Compliance Process: For human and 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.*

***Note that specific CITI certificates are required for human studies. Non-clinical trial human subjects studies must include certificates from the "Human Research" curriculum group (ex: Biomedical Research Investigators). The CITI Good Clinical Practice course is also accepted.**

9. Appendix Requirements

Items 1 and 2 are required for all applications.

Items 3, 4, and 5 do not pertain to all projects. However, when relevant, they are mandatory.

- 1) An [NIH Biosketch](#) must be submitted for all key personnel. Please follow the NIH “*Biosketch instructions – non-fellowship*” link and use the NIH “*Blank biosketch format – non-fellowship*” to format each biosketch. *5 page maximum for each individual Biosketch.*
- 2) A letter signed by your immediate supervisor including acknowledgement of their support for the project and providing assurance that sufficient protected time to complete the research will be available. *At least 10% effort during the period of performance is required. Percent effort should be clearly stated.*
- 3) Proof that IRB and/or IACUC protocol has been submitted for review and approval. Full approval is not necessary at time of application, however proof of official submission is required. IRB/IACUC approval are not required prior to application submission deadline but must be completed within 60 days of notice of grant award. *Note that all WVCTSI Pilot awards require final NIH approval before funds can be released and official proof of IRB/IACUC approval is required to obtain NIH approval. Therefore no project can start nor funds be released without proper compliance documentation.*
- 4) Any Principal Investigator submitting a full proposal that has previously received WVCTSI pilot grant funding, or INBRE pilot grant funding must include the following in their appendix:
 - a. A paragraph that, in layman’s terms, describes how this proposal differs from past funded projects. Please describe if this is a new project, or an extension of past funded projects.
 - b. Please list any and all publications that resulted from past funded pilot grants as well document any external grant submissions, and results of external grant submissions (funded, scored, not funded). If there are other items that demonstrate the productivity of past WVCTSI or INBRE funded pilot grants please describe them as well.

10. Final Checklist: Please enclose the WVCTSI Pilot Grant Application – Submission Checklist at the end of your application package to help ensure that all necessary documents are included.

11. Review and Selection Process

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 leadership (with NIH and external advisory committee approval), 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.

Funding Priorities

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

- Applications that have been favorably reviewed extramurally and/or by the WVCTSI that are re- submitted with clear responsiveness to previous critique and a plan for translational focus of the research.
- 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 (minimum 10% effort for the PI) 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.
- Thematic focus topics related to Addiction and resultant emerging epidemics (Hepatitis C), Cancer, Cardiovascular Disease, Chronic Lung Disease, Neuroscience and the risk factors associated with the aforementioned thematic focus topics.
- Applications in which Early Stage (ESI) and Junior Investigators propose pilot studies to obtain preliminary data for an extramural grant submission.
- Applications in which the PI has partnered with the West Virginia Practice Based Research Network (WVPBRN).
- Applications intended to stimulate innovation and commercialization

- 12. 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.
- 13. Reporting:** Co-PIs that receive a WVCTSI Pilot Award will be required to submit a progress report every three (3) months as defined by the project period of performance. A final progress report, invention statement and the final itemized expenditures are required for closeout of an award.

SUBMISSION VIA iLAB

In order to streamline and better track services, [WVCTSI implemented the use of the iLab platform](#). **We ask investigators to submit requests for services through iLab in order for us to best address your specific concerns.**

WVCTSI continues to offer Pilot 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).

A. To create an iLab account **using WVU credentials**:

1. Go to <https://wvu.corefacilities.org/account/login>
2. Sign in using your WVU credentials. This should re-direct you to the standard WVU login page.
3. Once logged in, select "[CTSI Community](#)" as your lab.
4. An iLab staff member will be in touch with you shortly to verify your account.

B. To create an iLab account for those **with WVCTSI Partner Sites** credentials:

1. Go to <https://wvu.corefacilities.org/account/984/signup>
2. Enter your email address, and agree to iLab's privacy and security policies.
3. Complete your personal information. Enter WVCTSI as your institution.

- For primary role, do NOT choose PI. Please select “Other”.
 - 4. Input “WVCTSI Partners” for your lab. If you are currently affiliated with a lab, please **do not select your personal lab** or input a new lab.
 - 5. For billing address, enter WVCTSI’s address: “PO Box 9102, Morgantown, WV 26506-9102”
 - 6. An iLab staff member will be in touch with you shortly to verify your account.
- C. To create an iLab account for those **with WVPBRN** credentials:
- 1. Go to <https://wvu.corefacilities.org/account/984/signup>
 - 2. Enter your email address, and agree to iLab’s privacy and security policies.
 - 3. Input your personal information, and enter “WVPBRN Community” as your institution.
 - For primary role, do NOT choose PI. Please select “Other”.
 - 4. Input “WVPBRN Community Group” for your lab. If you are currently affiliated with a lab, please **do not select your personal lab** or input a new lab.
 - 5. For billing address, enter WVCTSI’s address: “PO Box 9102, Morgantown, WV 26506-9102”
 - 6. An iLab staff member will be in touch with you shortly to verify your account.

To submit your application:

- 1. Log into iLab
- 2. Locate the Menu in the upper left corner (3 horizontal lines next to “Agilent CrossLab) and click on it
- 3. Click on “Core Facilities”
- 4. WVU credentials: scroll down to the bottom of the screen to locate WVCTSI cores.
Non-WVU credentials: Locate the “View” drop down menu on the right side of screen and select “Cores at other institutions”. It will take a few minutes for everything to load. Once it’s done, type “WVCTSI” in the search box (next to the View drop-down menu)
- 5. Select “WVCTSI Investigator Development Services”
- 6. You will see multiple tabs on the right half of the screen. Make sure to be on “Request Services” rather than “About Our Core”
- 7. Various services can be accessed here, including general WVCTSI consultations and Pilot information meetings.
- 8. To submit an LOI or proposal, scroll down to “Pilot Projects Grant Submission”
- 9. Click on the “initiate request” button on the left
- 10. Fill out the necessary fields and attachments
- 11. Click “submit”

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!

CONTACT INFORMATION

Updated February 5, 2019

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

Contact	Phone Number	Email
Camille Charlier, MS <i>Pilot Grant Program Coordinator</i>	304-293-4275	ccharlie@hsc.wvu.edu
Meghan Reeves, MPH <i>Investigator Development Manager</i>	304-293-6581	mreeves1@hsc.wvu.edu