West Virginia Clinical and Translational Science Institute

Spring 2020 Research Scholar RFA

DEADLINES:	**QUICK LINKS**
LOIs Due: **December 20 2019** *Full Applications:* **March 27, 2020 by 5PM**	General Overview & Letter of Intent Full Text Announcement Eligibility Application Instructions Human Subjects Protection Budget Review and Selection Process iLab Instructions
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PART 1. OVERVIEW

The purpose of this program is to develop principal investigators in the clinical and/or translational sciences with the desired outcomes of peer-reviewed publications and submission of applications for mentor-sponsored (e.g. NIH K-type) awards and eventually independent federal (e.g. NIH R-type) awards. The award is available to persons who have demonstrated considerable potential to become independent researchers and may benefit from additional mentored research experience in a productive scientific setting, as well as to newly independent researchers. Research Scholars are eligible to receive salary support for protected research time from WVCTSI as well as a modest research expense budget. Pre-existing, committed departmental protected time for research/scholarship must remain in place for the duration of the Research Scholar appointment and the WVCTSI salary support* is intended to supplement and enhance the departmental commitment.

Required Letter of Intent (LOI)

To better serve those applying for West Virginia Clinical and Translational Science Institute Research Scholar Program, Letters of Intent (LOI) will be required from interested Principal Investigators. The proposed projects should address health care needs of West Virginia. Examples include, but are not limited to, the following health care issues:

- Addiction and Resultant Emerging Epidemics (hepatitis C)
- Cancer
- Cardiovascular Disease
- Chronic Lung Disease
- Neuroscience

The LOI must follow the template found here.

LOIs are required and must be submitted via iLab as a single PDF document on or before the deadline.

The LOIs are used to facilitate review planning. Additionally, they are a valuable feedback tool to further strengthen the full proposal applications. Investigators may be asked to meet with WVCTSI to review their LOI and discuss specific aspects of their proposal.

All investigators will receive an email notification informing them whether they are invited to submit a full proposal or not.

Investigators whose projects are consistent with our mission and the scope of this RFA may be invited to submit full proposals. Unsolicited full proposals from PIs who do not submit a LOI will not be reviewed nor considered for funding.

Budget

For this funding cycle, the budget is limited to a maximum of $25,000 for project costs in total direct costs for twenty-four (24) months. PI Salary request is separate to project costs.

PART 2. FULL TEXT ANNOUNCEMENT

Funding Opportunity Description

WVCTSI is accepting Research Scholar 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 twenty four (24) 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.

Application Instructions

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.

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 Full Applications

SECTION	DESCRIPTION	CONTENT LIMIT
Face Page	Please use the Cover Sheet form	N/A
Cover Letter	a) Career Goals: Long-term (5-10 years) and short-term (1-2 years) b) Description of commitment to a career in research c) Current professional responsibilities and their relationship to the proposed activities during the award period; discussion of specific changes in daily duties if appointed as a WVCTSI Research Scholar d) Commitment to a focused research project and plan for limiting administrative or competing responsibilities during Research Scholar appointment e) Prior training and relationship to the applicant's immediate objectives and long- term career plans	

	f) Research activities to date: including general information on publications, proposal submissions, awards and other relevant efforts g) Evidence of potential to develop into an independent research investigator h) External funding plan to sustain research program after Research Scholar period of performance (specific funding mechanism, target institute, and other relevant info) As applicable include copy of FOA in appendix of application	
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
Letters of Support	Letter of Support Guide Here: Letters should be submitted with the full application package from each of the following individuals. a) Primary Mentor and each mentoring team member b) Department Chair, Division Head (if applicable), Center Director or Signature Program Lead	N/A
WVCTSI Mentoring Agreement	Team Mentoring Agreement	NA
Abstract/Summary	a) Your background and career development, research background b) Specific Aims and hypothesis, unique features/innovation, methodologies, expected results c) Generalizability, Relation to the field, general significance	30 lines written in plain/lay language
Specific Aims and Proposal (Candidate Information and Research Strategy)	Please use the NIH PHS 398 Continuation Page forms (Continuation Format Page) and include the sections below	6 pages total (see breakdown below)
	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.	1 page (Specific Aim) 6 pages (Candidate Information and Research Strategy combined)
	B. Candidate Information Organize the Candidate Information in the following way:	
	1. Candidate's Background a) Describe the candidate's commitment to a health-related research career. Describe all the candidate's professional responsibilities in the grantee institution and elsewhere and describe their relationship to the proposed activities on the career award. b) Describe prior training and how it relates to the objectives and long-term career plans of the candidate. c) Describe the candidate's research efforts to this point in his/her research career, including any publications, prior research interests and experience. d) Provide evidence of the candidate's potential to develop into an independent investigator.	
	2. Candidate's Goals and Objectives	

	a) Describe a systematic plan: (1) that shows a logical progression from prior research and training experiences to the research and career development experiences that will occur during the career award period and then to independent investigator status; and (2) that justifies the need for further career	
	3. **Candidate's Plan for Career Development/Training Activities During Award Period** a) The candidate and the mentor are jointly responsible for the preparation of the career development plan. A career development timeline is often helpful. The mentor and any co-mentors may form a mentoring team to assist with the development of a program of study or to monitor the candidate's progress through the career-development program b) The didactic (if any) and the research aspects of the plan must be designed to develop the necessary knowledge and research skills in scientific areas relevant to the candidate's career goals. c) Describe the professional responsibilities/activities including other research projects beyond the minimum required effort. Explain how these responsibilities/activates will help ensure career progression to achieve independence as an investigator.	
	B. Research Plan a) A sound research project that is consistent with the candidate's level of research development and objectives of his/her career development plan must be provided. The research description should demonstrate the quality of the candidate's research thus far and also the novelty, significance, creativity and approach, as well as the ability of the candidate to carry out the research. b) The application must also describe the relationship between the mentor's research and the candidate's proposed research plan. c) If the applicant is proposing to gain experience in a clinical trial, ancillary study to a clinical trial or a clinical trial feasibility study as part of his or her research career development, describe the relationship of the proposed research project to the clinical trial. 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.	
	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 a) Explain how the project is of translational significance to the health of persons in West Virginia and/or Appalachia.	

	b) Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice. c) Describe how relevant concepts, methods, technologies, treatments, services, or preventative interventions will be changed if the proposed aims are achieved.	
	4. Innovation a) Explain how the application challenges and seeks to shift current research or clinical practice paradigms. b) 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). c) Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions.	
	5. Approach a) 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. b) Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. c) If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work. Clearly describe how each partner will be engaged in the development and/or implementation of the pilot study.	
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.	No limit
Budget & Budget Justification	Budget Template	No limit

Budget

General

- Personnel: if possible, please name co-investigators, graduate students (stipends are not an eligible expense), 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: $1,500.00 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, clinical trainees, post-doctoral, and clinical fellows are permitted. *Applicants must account for fringe benefit costs when considering research assistant salary levels.*
- 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

- * Funding is not available for student stipends.
- Funding will not be awarded as bridge funding for ongoing, competitive projects.
- Facilities and administrative costs, also known as indirect costs, are not permitted.

* **Note on students:** Unfortunately, the NIH does not allow us to pay for support for graduate students who are receiving a stipend or a salary. This policy applies to all students, i.e. PhD, masters, and undergraduate. We do however allow for graduate or undergraduate students who are NOT on salaried assistantships to be hired as a lab technician or student worker paid **hourly** on the pilot grant.

If you are unsure whether a student can receive funding from the award, please contact us.

Table 2. Additional Content As Applicable

SECTION	DESCRIPTION	CONTENT LIMIT
Human Subjects Protection	**All Human Subjects studies must include:** 1. The "Human Subjects Template for WVCTSI Funded Projects" form downloadable from the WVCTSI website. **Reference information concerning NIH definitions of Human Subject research and Clinical Trials can be found here.** * Note: Clinical Trials MUST include a study timeline (Section 2.7) 2. The NIH PHS 398 Inclusion Enrollment Report, to be downloaded from the WVCTSI website and completed using the instructions found here. We typically recommend using U.S. Census data for estimates as this form is meant to be reflective of your study sample plans and expectations. Note that this form does *not* constitute a formal commitment to an unchangeable sample size or demographics.	N/A
Clinical Protocol	**Clinical Trials MUST submit a clinical protocol in addition to their Research Strategy.** • Please use the WVU IRB form "Investigator Initiated Protocol Template". • WVU investigators can also use Protocol Builder, an online tool to build clinical protocols for a variety of study types. Please refer to the Protocol Builder section at the bottom of the WVU IRB Guidance page for additional information.	No limit
Vertebrate Animals	Please use NIH PHS 398 Continuation Page form(s) (Continuation Format Page) and the NIH Animal Welfare instructions. The following headers MUST be clearly labeled: • Description of Procedures • Justifications • Minimization of Pain and Distress • Method of Euthanasia	No limit
Proof of IRB/IACUC Submission	Proof that IRB and or IACUC protocol has been submitted for review and approval. Full approval is not necessary at time of application but is expected within 60 days following award notification.	

Review and Selection Process

Submitted application will undergo peer review. Finalists will be asked to give a presentation and participate in an interview.

A. Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the scholar 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.

- Candidate
- Clinical/Translational Focus
- Feasibility of Research Plan
- Potential for Extramural Funding
- Mentoring and Institutional Environment
- Career Plan
- Clinical Trials only – Study Timeline

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.

- Protections for Human Subjects
- Inclusion of Women, Minorities, and Children
- 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 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.

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.

PART 3. iLab INSTRUCTIONS & CONTACT INFORMATION

CONTACT INFORMATION

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

ATTENTION
In order to streamline and better 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.**

WVCTSI continues to offer Pilot Grant consults 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. If you are affiliated with another lab at WVU, please **do *not* select your personal lab**. You will not be able to access WVCTSI services if you do not choose CTSI Community.

B. 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 "WVPBNRN 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.

C. To create an iLab account for Partner Sites with **non-WVU and non-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 "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.
7. For the question "Is there another person in your lab who helps manage lab memberships, fund assignments, and spending approval?" choose "No."
8. Accept iLab's Terms and Conditions, and submit your registration. An iLab staff member will be in touch with you shortly to confirm your credentials.
9. Let Meghan Reeves know if you have received your email notification from iLabs and you will be granted access to the Core you need access to.

To submit a Research Scholar Letter of Intent or Full 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 Research Scholar 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!

Contact	Phone Number	Email
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