Updated February 23, 2018

West Virginia Clinical and Translational Science Institute Collaboration Grant Competition RFA

PART 1. OVERVIEW INFORMATION

The goal of this Request for Applications (RFA) is to support clinical and translational pilot projects relevant to improving health in West Virginia and Appalachia. This RFA focuses on collaborative projects between partner sites across West Virginia.

DEADLINES	
Letter of Intent (LOI)	**Full Application**
Tuesday March 31st, 2018 by 5PM	Tuesday May 15th, 2018 by 5PM

Applicants are encouraged to meet with the Investigator Development Manager prior to application submission.

Please refer to the last page of this RFA for updated contact information and procedure, including our new communication platform "iLab".

Required Letter of Intent (LOI)
To better serve those applying for West Virginia Clinical and Translational Science Institute pilot project funding, 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 should follow the template found here and include the following sections:

1. Cover Page
2. Project Abstract
3. Proposed Project Description - In one page or less, please describe the rationale and health care issue addressed, proposed project objectives, and potential impact addressed by the proposed study
4. NIH Biosketches of both Co-PIs

Eligible Partner Sites:
Marshall University (MU), West Virginia School of Osteopathic Medicine (WVSOM), and West Virginia University (WVU) – Including Morgantown, Eastern, and

Charleston Campuses.

Additional Information on Eligibility

- **A minimum of two Principal Investigators (PI)** are required for this funding opportunity, **coming from at least 2 different participating institutions** (Marshall University (MU), West Virginia School of Osteopathic Medicine (WVSOM), West Virginia University (WVU - all campuses)).
  - One of the two Co-PIs is designated as the lead/contact PI; her or his name should appear on the cover page.
  - **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.**
- All Co-PLs/Co-PIs 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.
- All Early Stage Investigator (ESI) PIs must complete the one page attachment with signature from proposed mentor. Mentorship Agreement Plan can be found here. Early Stage Investigator(ESI) Principal Investigators, as defined by the NIH as a new investigator who has completed his or her terminal research degree or medical or other professional residency—whichever date is later—within the past 10 years and has not yet been awarded a substantial, competing NIH research grant.

LOIs are required and must be submitted as a single PDF document on or before the deadline. LOIs should be submitted via the iLab website (see instructions at the end of this RFA).The letters will be used to facilitate planning for the proper reviewers needed for the evaluation of the full proposals. In addition, the LOIs will be used to provide feedback to further strengthen the full proposal applications. Some investigators will be asked to meet with Pilot Projects Program Senior Scientific Advisors to review their LOI and provide specific feedback regarding their submitted protocol.

Following review of submitted LOIs, all PIs will receive an e-mail notifying them that their LOI has been reviewed, and including any additional feedback from the LOI reviewers.

Unsolicited full proposals from PIs who do not submit an LOI by the 03/06/2018 deadline will not be reviewed nor considered for funding.

Budget

For all funding cycles, the budget is limited to a maximum of $50,000 in total direct costs for twelve (12) months, with each site submitting similar budget totals. Applicant teams are encouraged to submit proposals with budgets that are approximately equally supported from 2 institutions, however exceptions may be made on a case by case basis.

Compliance Requirements for a Full Proposal

PIs submitting a full proposal in response to this RFA must include CITI certification for investigators conducting research or collecting outcomes with human and/or animal subjects as well as documentation of IRB and/or IACUC protocol submission. Documentation for these requirements should be included in the Appendix of the application. IRB/IACUC approval are not required prior to application submission deadline but must be completed within 30 days of notice of grant award.

PART 2. FULL TEXT ANNOUNCEMENT

Section I. 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 twelve (12) months.

Section II. Eligibility Information

For both the LOI as well as the full proposal, PI eligibility is limited to the following:

- A combination of two of the following institutions MU, WVSOM, and WVU (all campuses) should be represented by one Co-PL/Co-PI each on the proposed research team. **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.**
  - All Co-PIs 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 West Virginia Health Grant Partnership projects.
  - Any Early Stage Investigator (ESI) applicants are required to submit a one page mentoring agreement plan in the proposal appendix.

Additional Information on Eligibility–Number of Applications
Co-PLs/Co-PIs can only submit one LOI under this RFA. Individuals may serve as co-investigators or project team members on more than one proposal.

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.

*** 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.

Resubmissions

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 should be sent 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. **Table of Content:** Please use the NIH PHS 398 Research Grant Table of Contents (Form Page 3). Please label as "N/A" any item not specifically required in this RFA.

4. **Approach/Research Plan:** Please use the NIH PHS 398 Continuation Page forms (Continuation Format Page). This section is limited to a total of 6 pages: 1 page for the **Specific Aims/Objectives** and 5 pages for 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.

As applicable, also include the following information as part of the Research Strategy, keeping within

the three sections listed above: Significance, Innovation, and Approach.

- **Preliminary Studies**: Please include information on any preliminary studies, if available. Discuss the PI's preliminary studies, data, and/or experience pertinent to this application. Preliminary data can be an essential part of a research grant application and help to establish the likelihood of success of the proposed project. This is not a requirement.
- **Translational Nature:** Please include a paragraph at the end of application on the translational aspects of your application. Include a plan for translating and disseminating findings back to practitioners and/or community.

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 5 pages maximum of the Approach/Research Plan above, nor is it limited in length.*

6. **Human Subjects Protection and Vertebrate Animals.**

CHANGE: Please note that due to changes in NIH regulations, the "Human Subjects Protection Section" has now been replaced by the "Clinical Trials – WVCTSI Form".

Please download the Clinical Trials – WVCTSI Form from the WVCTSI website. Complete the form and include it as part of your PDF application packet.

- For reference, information concerning NIH definitions of Human Subject research and Clinical Trials can be found here.

ADDITIONALLY: Please complete the NIH PHS 398 Inclusion Enrollment Report using the instructions found here. 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. 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). For all funding cycles, the budget is limited to a **maximum of $50,000** in total direct costs with a performance period of **twelve (12) 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 Co-PIs or other investigators with faculty appointments.
  - Co-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 towards the West Virginia Health Grant Partnership project.
- 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.*

- **For WVU Researchers:** Certification of CITI training for protection of human subjects is required if the proposed projects includes research with humans and must be included in the Appendix of your application.
- **For Non-WVU WVCTSI Organizations:** Certification of CITI training for protection of human subjects is required if the proposed projects includes research with humans and must be included in the Appendix of your application.

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) Mentorship Agreement Plan - To facilitate the effectiveness of the WVCTSI Pilot Grant Program in enhancing the research development of newly appointed faculty investigators, new investigators must provide a letter of endorsement and collaboration from a senior investigator who is willing to serve as a mentor for the applicant over the course of the project.
   - This person must possess a M.D., Ph.D., Pharm.D, or other doctoral degree *and* must have sufficient clinical research expertise to serve as a mentor to the applicant.
   - The letter should reflect the amount of time the mentor is willing/able to direct to this role as well as the specific types of activities that will be involved. These activities should include reviewing progress on the project, reviewing initial data, helping plan for future project funding after the pilot phase, discussing relevant research articles or related activities.
   - Launch Pilot Grants application from ESIs as well as junior investigators should be reviewed by her/his Mentoring Team prior to submission to the Clinical and Translational Pilot Grants program. The mentor should indicate this action was taken in the letter of support from the mentor.
   - It is NOT required that the mentor have funded effort.
   - **ESI PIs must complete the one page attachment with signature from proposed mentor.**

4) 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.

5) Outline of clinical protocol – If the study is an investigator-initiated clinical trial and not described in the proposal.

6) 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.

Section III. Application Review Information

Only the review criteria described below will be considered in the review process; the review panel will be comprised of subject matter experts from MU, WVSOM, and WVU as well as any additional subject matter experts from other institutions/organizations. Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on clinical care or the research field(s) involved with the proposed project.

Scored Review Criteria
Reviewers will consider each of the review criteria below and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. (E.g., a project that by its nature is not innovative may be essential to advance a field.)

1. *Significance*
Does the project address an important problem or a critical barrier to progress in the field? Does the project address an important problem or a critical barrier to addressing health disparities in West Virginia/Appalachia?
If the aims of the project are achieved, how will scientific knowledge, technical capability, clinical practice and/or patient and community health be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services or preventative interventions that drive this field?

2. *Innovation*
Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation or interventions? Are the concepts, approaches or methodologies, instrumentation or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation or interventions proposed?

3. *Approach*
Are the overall strategy, methodology and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of children, justified in terms of the scientific goals and research strategy proposed?

4. *Environment*

Will the environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the environment, subject populations, or collaborative arrangements?

Additional Review Criteria

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

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials. For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human
Subjects.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section.

Biohazards/Biosafety

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment and, if needed, determine whether adequate protection is proposed.

Radiation Safety and Hazardous Materials

Projects involving the use of radioactive material must be reviewed and approved by the Radiological Safety Committee before any materials can be ordered and work begun at any institution. Any questions pertaining to WVU policy and procedures can be answered by referring to:

http://www.hsc.wvu.edu/rsafety/. For questions pertaining to MU policies, please contact Dr. William McCumbee at mccumbee@marshall.edu.

Budget and Period of Support
Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

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.

A. 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.

Section IV. Award Administration Information

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: 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.

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 recently implemented the use of the **iLab** platform. **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 **without** WVU credentials:

1. Go to https://wvu.corefacilities.org/account/login
2. At the upper right hand corner of the page, hover over "Register" and select "Register for an iLab account."
3. Input your name and email, and enter WVCTSI as your institution.
4. Input your role as "Other". For PI, input Meghan Reeves (mreeves1@hsc.wvu.edu)
5. For the question "Is your lab already registered with iLab?" type in WVCTSI Partners. *If you are affiliated with another lab, please DO NOT select your personal lab, and do NOT input a new lab.*
6. For the question "Is there another person in your lab who helps manage lab memberships, fund assignments, and spending approval?" choose "No."
7. 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.
8. 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 request Pilot Core services:

1. From the list of cores, select "WVCTSI Investigator Development Services." If this is your first time submitting a request to WVCTSI, iLab may prompt you to request access to the core. If so, a WVCTSI team member will approve your access request within 24 hours.
2. In the upper right hand corner, click on the "Request Services" tab.

3. Select “Pilot Projects Program Request”, and initiate the request. For general inquiries, select “WVCTSI Consultation and Service Request”. For LOI and full proposal submissions, select “Pilot Projects Grants Submission”.
4.
5. Complete the request form in full, then click “submit.” Please do not enter any payment information, all WVCTSI services are completely free to WVCTSI members. A WVCTSI staff member will reach out to you to follow up with your request as soon as possible.

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 gladly assist you.

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