



West Virginia Clinical and Translational Science Institute 2023 LAUNCH Grant Competition RFA

DEADLINES:

Letters of Intent:

June 28, 2023 by 5PM

Full Applications:

September 7, 2023 by 5PM

CONTACTS:

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PART 1. OVERVIEW & LETTER OF INTENT

The goal of this Request for Applications (RFA) is to accelerate the translation of intellectual property developed by West Virginia Clinical and Translational Science Institute (WVCTSI) researchers into realized inventions as well as patents.

The technology to be further developed under this RFA must be the subject of a WVU, Marshall University, West Virginia School of Osteopathic Medicine, or CAMC Health and Research Institute Invention Disclosure and Assignment. The subject technology must require additional development to be viable for commercialization.

Questions regarding the proposed projects being appropriate for this funding opportunity, please contact Erienne Olesh via email at Erienne.Olesh@mail.wvu.edu.

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. **Applicants to the Launch Pilot grant must also include a notice of Invention Disclosure and Assignment approval from their respective home institution.**

- **WVU and WVSOM:** For questions regarding this approval letter, or to obtain a letter, please contact Erienne Olesh at Erienne.olesh@mail.wvu.edu.
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- **Marshall University:** Investigators at Marshall University should contact the Technology Transfer Office, tto@marshall.edu, with any questions.

Only the top scoring LOIs that address one or more of the following funding priority areas will be invited to submit a full proposal:

- Poised for commercialization with specific targeted demonstration or test results.

- The technology can be developed with available resources provided by this grant to the point that it can be used for additional commercialization funding or be licensable within 9 months of receipt of the award.
- The initial research scale results require the development of a prototype.
- Project has progressed to the point where typical academic research funding sources are no longer applicable, but the project has yet to reach a commercial value inflection point; and,
- Must demonstrate that if the project is successful the results will be a technology that has interested licensing or funding partners.

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 June 28.

The LOI will be used to screen applicants based on scientific merit as well as WVCTSI research thematic alignment. After review, only applicants with scientific merit and focused research thematic topics will be asked to submit full proposals. This requirement will help to ensure that potential projects are in line with WVCTSI goals and target areas.

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 will be invited to submit full proposals. Unsolicited full proposals from PIs who do not submit an LOI will not be reviewed nor considered for funding.

Human subject project applicants are required to present the clinical component of their project at the PI Academy's Idea Lab before the full application due date. Please reach out to our Training Manager, Debbie Lee, at debbie.lee@hsc.wvu.edu to schedule a time to present.

Budget

For this funding cycle, the budget is limited to a maximum of \$50,000 in total direct costs for nine (9) months. PIs can request an additional \$5,000 if they include a six-week or longer research experience for a medical student as part of the project.

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. Documentation for these requirements should be included in the Appendix of the application. IRB/IACUC approval are not required prior to application submission deadline. For animal studies, proof of IACUC submission is required in the application. ***Note that all WVCTSI Pilot awards require official proof of IRB/IACUC approval before project start. Therefore, no project can start, nor funds be released without proper compliance documentation.***

PART 2. FULL TEXT ANNOUNCEMENT

SECTION I. Funding Opportunity Description

WVCTSI is accepting Innovation Pilot Project Funding applications for clinical and translational research focusing on accelerating the translation of intellectual property developed by WVCTSI researchers to the market.

The following priorities for Launch 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.
- WVCTSI thematic focus topics related to Addiction, Alzheimer's Disease, emerging epidemics (e.g., SARS-CoV-2, HIV, Hepatitis C), Cancer, Cardiovascular Disease (including stroke), Chronic Lung Disease and the risk factors associated with the aforementioned thematic focus topics.
- Applications intended to stimulate innovation and commercialization.

SECTION II. General Guidelines

Faculty members invited to submit full proposals need to include projects that address the specific aims of the WVCTSI. To better address the specific aims of the WVCTSI, PIs will be invited to submit full applications that address one of the following funding priority areas:

- Addiction
- Emerging Epidemics (e.g., SARS-CoV-2, HIV, Hepatitis C)
- Cancer
- Cardiovascular Disease (including stroke)
- Chronic Lung Disease
- Alzheimer's Disease

Application Types Allowed

1. **New** - An application that has not been previously submitted to any WVCTSI grant program. All new applications will be reviewed competitively using the evaluation criteria described in Section IV – Application Review Information.
2. **Resubmissions** - An application that has previously been submitted to Launch 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 Launch Pilot Grants Program at the same time.

Award Project Period

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

SECTION III. Eligibility Information & Resubmissions

PI eligibility criteria:

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

All Early-Stage Investigator (ESI) PIs **must** complete the one page attachment with signature from proposed mentor. The 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.

Restrictions

- The following personnel are not eligible to serve as PIs but may be co-investigators: investigators-in-training including residents, post-doctoral fellows, clinical fellows, and faculty member(s) with courtesy appointments.
- Pilot projects may not overlap with other ongoing WVCTSI-funded projects.
- *The Project lead for Pilot projects may not concurrently have funding from other IDeA Program award mechanisms (e.g. INBRE, COBRE).*
- 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.

Past Pilot Funded Principal Investigators

Any Principal Investigator submitting a full proposal that has received past WVCTSI and/or INBRE pilot grant funding must include the following in their appendix:

1. A paragraph that, in layman's terms, **clearly describes how this proposal differs from past funded projects**. Please describe if this is a new project, or an extension of past funded projects.
2. Please list any and all publications that resulted from past funded pilot grants as well document any external grant submissions, and subsequent results (funded, scored, not funded). If other items demonstrate the productivity of past WVCTSI or INBRE funded pilot grants, please describe them as well.

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 have not 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.

Number of Applications

For the Launch Pilot grant, PIs can submit as many LOIs as she/he can prepare, but each PI will only be invited to submit one full application by the submission date.

Resubmissions

Any application previously been submitted to WVCTSI Pilot Grants Program, but not funded is eligible for resubmission **once**. PIs submitting a revised proposal must respond to the previous panel review summary and will have one additional page within their application to do so.

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***.

Regardless of designation, applications appearing to be resubmissions 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 during that funding cycle.

If you are planning on completing a resubmission, please contact the WVCTSI team prior to re-submitting your application.

SECTION IV. Application and Submission

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.

Grantsmanship: Use English and avoid jargon. If terms are not universally known, spell out the term the first time it is used, and note the appropriate abbreviation in parentheses. The abbreviation may be used thereafter.

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 NIH PHS 398 Face Page form (Form Page 1)	N/A
Project Summary, 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)	Project Summary – 30 lines Relevance – 3 sentences
Approach/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. <u>Applicants must identify how the study objectives and outcomes are of benefit to West Virginia/Appalachian patients and communities.</u>	1 page
	B. Research Plan Organize the Research Plan in the specified order and using the instructions provided below. <u>Start each section with the appropriate section heading: Hypothesis, Background, Significance, Innovation, Commercialization and Approach.</u>	5 pages
	1. Background	

	Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.	
	2. Hypothesis Clearly and briefly define the hypothesis of the project.	
	3. Significance <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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. Commercialization <ul style="list-style-type: none"> • Describe the commercial potential for this technology. Include information on research/work to date that has advanced the technology down the commercial pathway. What future plans are there for this technology to advance it towards a viable commercial product? If awarded, how will the grant dollars directly move the technology closer to the market? • Describe any other resources or programs you have participated in to help strengthen the commercial potential of this product, including any innovation or entrepreneurial programs. • Provide information and details regarding potential market size of the technology. 	
	6. Approach <ul style="list-style-type: none"> • 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. • 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. 	

	<p>As applicable, also include the following information as part of sections 3, 4, and 5 listed above:</p> <ul style="list-style-type: none"> ○ 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. 	N/A Content to be incorporated in Significance, Innovation, and Approach sections.
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
Disclosures	Declare any conflict of interests relevant to this project. If you do have conflicts, please disclose, and describe them. Specifically, if you have any financial or personal interest in a company or business that would be supported or benefit from this grant, that information must be disclosed. Examples of conflicts can be found here: coi-policy-wvu-hsc-2-21-1.pdf . For questions, please reach out to Meg Haller, mehaller@hsc.wvu.edu .	No limit
NIH Biosketch	Please follow the NIH "Biosketch instructions – non-fellowship" link and use the NIH "Blank biosketch format – non-fellowship" to format each biosketch.	5 pages each
Letter of Support	A letter signed by your immediate supervisor acknowledging their support for the project and providing assurance that sufficient protected time to complete the research will be available. <i>At least 10% effort during the period of performance is required. Percent effort should be clearly stated.</i>	No limit
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.	

Budget

General

- **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.
- WVCTSI Pilot Grants allow up to 10% of an award to be used for PI salary support (including fringe benefits). Any salary support requested from the grant must be matched by the PI's home department in the form of matching funds. At this time, no faculty Co-I salary may be charged to the grant.
- * 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 (\$2,000 maximum)
- Conference Travel (\$4,000 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 pilot grant, please contact us.

Table 2. Additional Content As Applicable

SECTION	DESCRIPTION	CONTENT LIMIT
Human Subjects	All Human Subjects studies must include:	N/A

Protection	<p>1. The “Human Subjects Template for WVCTSI Funded Projects” form downloadable from the WVCTSI website.</p> <p>Reference information concerning NIH definitions of Human Subject research and Clinical Trials can be found here.</p> <p>* Note: Clinical Trials MUST include a study timeline (Section 2.7)</p> <p>2. The NIH PHS 398 Inclusion Enrollment Report, to be downloaded from the WVCTSI website and completed using the instructions found here.</p> <p>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 <i>not</i> constitute a formal commitment to an unchangeable sample size or demographics.</p>	
Clinical Protocol	<p>Clinical Trials MUST submit a clinical protocol in addition to their Research Strategy.</p> <ul style="list-style-type: none"> Please use the WVU IRB form “Investigator Initiated Protocol Template.” <p>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.</p>	No limit
Vertebrate Animals	<p>1. 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:</p> <ul style="list-style-type: none"> Description of Procedures Justifications Minimization of Pain and Distress Method of Euthanasia <p>2. Proof of IACUC submission.</p>	No limit
Compliance	<p>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 <u>anyone actively involved in the project regardless of title.</u></p> <p><i>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.</i></p> <p>Please include the certificates listed below as applicable to your project.</p>	N/A
	<p>Human Studies – Non-Clinical Trials</p> <p>A minimum of one course from the “Human Research” curriculum group</p> <p>Human Studies – Clinical Trials</p> <p>A minimum of one course from the “Human Research” curriculum group AND the Good Clinical Practice (GCP) module.</p> <p>See NIH clinical trial criteria here.</p>	
	<p>Vertebrate Animals</p> <p>Any course from the Animal Research curriculum groups as applicable to your project.</p>	

	ATTENTION: WVCTSI does NOT have access to investigator's CITI certificates or IRB/IACUC records. Applicants MUST submit required documents directly to the WVCTSI Pilot team.	
Mentorship Agreement Plan	<p>Please use the Mentorship Agreement Plan.</p> <p>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.</p> <ul style="list-style-type: none"> • This person must possess a M.D., Ph.D., Pharm.D, or other doctoral degree <i>and</i> 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 their 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. 	N/A
Prior WCTSI/INBRE Pilot Funding	<p>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:</p> <ol style="list-style-type: none"> 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. 	1 page
Resubmission	Any application that meets the guidelines of a resubmission should include a response to previous reviewer comments.	1 page

Review and Selection Process

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

A. Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration

of the following review criteria and additional review criteria (as applicable for the project proposed).

B. Scored Review Criteria

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

- Significance
- Investigator(s)
- Innovation
- Approach
- Environment
- External Competitiveness
- Clinical Trials only – Study Timeline
- Commercial Potential – potential of project to translate into a viable product

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

C. Additional Review Criteria

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

- 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 (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.

D. Funding Priorities

To provide broad support for clinical and translational research across the WVCTSI network and to address program goals, the PPP will provide a prioritization for scored applications. These prioritizations will: (1) ensure that the highest quality research is supported, (2) provide a focus on WVCTSI priority health areas, and (3) promote clinical and community-based research projects. To address these priorities, several strategies will be used, including score enhancement and administrative ranking. Scores will be enhanced by 0.25 points for each of the following categories, not to exceed a maximum enhancement of 1.0 point: (1) application studies a WVCTSI priority health area, (2) a clinician-led project, (3) a partner institution PI, (4) the PI is an ESI, and (5) projects that utilize the WVPBRN.

Award Notices

All awards are contingent upon receipt of NIH funding of the WVCTSI competitive renewal application. 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.

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 through 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 “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.

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 Meg Haller 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 Pilot grant 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 to Pilot Projects Grant Submission and select "initiate request"
7. Complete the form and click Submit
8. You will be automatically redirected to your list of Requests. Make sure that it has indeed been submitted. If the request is labeled as Waiting to Submit, click on label and select submit one more time.

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

Contact	Email
Meg Haller Pilot Grants Program Coordinator	mehaller@hsc.wvu.edu