Updated September 24, 2018

West Virginia Clinical and Translational Science Institute & West Virginia University Cancer Institute OPEN Grant Competition RFA for Cancer Research

PART 1. OVERVIEW & LETTER OF INTENT

The goal of this Request for Applications (RFA) is to support clinical and translational pilot projects for mid-career cancer investigators, in order to generate preliminary data for external NIH applications, and with the ultimate goal of improving health in West Virginia and Appalachia.

NOTE: West Virginia University Cancer Institute (WVUCI) membership is required. The application form for membership can be found here.

DEADLINES	
Letter of Intent (LOI)	**Full Application**
Monday, November 5 2018 by 5PM	Monday, January 7 2019 by 5PM

Applicants are encouraged to meet with the Investigator Development Manager (Meghan Reeves, MPH) prior to application submission.

The present RFA is designed for mid-level faculty members as defined by having had a faculty appointment for at least 5 years (no maximum limit). Investigators who do not meet this requirement are NOT eligible for this funding opportunity.

Note: WVCTSI offers several different types of funding opportunities throughout the year. Investigators interested in other health care areas, without a WVU Cancer Institute appointment, and/or not qualifying as mid-level faculty can learn more about these opportunities on the WVCTSI website.

Required Letter of Intent

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.

Letters of Intent, and subsequent proposals, submitted in response to this RFA **MUST** focus on cancer, including:

- Cancer clinical research
- Cancer prevention and early detection research
- Laboratory based cancer research

Translational research efforts that bridge at least two of these three areas of inquiry are especially requested.

The LOI should 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 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.

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.

Budget

For this funding cycle, the budget is limited to a maximum of $50,000 in total direct costs for up to twenty-four (24) months. The budget is not intended to provide salary support.

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 60 days of notice of grant award. *Note that all WVCTSI Pilot awards require final NIH approval before funds can be released and official proof of IRB/IACUC approval is required to obtain NIH approval. Therefore no project can start nor funds be released without proper compliance documentation.*

Past Pilot Funded Principal Investigators

Any Principal Investigator submitting a full proposal that has received past WVCTSI pilot grant funding (anytime), or INBRE pilot grant funding (anytime) 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 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.

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

PART 2. FULL TEXT ANNOUNCEMENT

Funding Opportunity Description

WVCTSI and the WVU Cancer Institute are accepting Pilot Project Funding applications for clinical and translational research focusing on cancer at it relates to West Virginia and Appalachia at large. Of note, projects with significant laboratory bas ed 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.

The NIH definition of Cancer prevention and control research includes:

- Research on cancer prevention and control and the surveillance and monitoring of the incidence, mortality, and morbidity of cancer.
- The primary research areas are chemoprevention, nutrition and diet, screening and early detection, community oncology, rehabilitation and pain management, cancer control applications, special populations, and surveillance.

Award Project Period

The scope of the 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. 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.

- **The PI must be a WVUCI member**, although co-Investigators may include WVU faculty outside of the WVUCI and/or researchers with appointments at other institutions. Note that WVUCI membership is open to all WVU faculty members, Health Sciences Center affiliated schools, and WVU colleges.
- The present RFA is designed for mid-level faculty members as defined by having had a faculty appointment at WVU or another research institution for at least 5 years (no maximum limit).

Investigators who do not meet those requirements are NOT eligible for this funding opportunity. If interested in WVCTSI funding, these individuals can learn more about other opportunities on the WVCTSI website.

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, COBRE, 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 via iLab as a single PDF document by the close of business hours (5:00 pm EST) on or before the deadline date. The application must include the following:

1. **Face Page:** Please use the NIH PHS 398 Face Page form (Form Page 1).

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

3. **Approach/Research Plan:** Please use the NIH PHS 398 Continuation Page forms (Continuation Format Page). This section is limited to 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.

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.

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.

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

All Human Subjects studies must include:

1) The Clinical Trials – WVCTSI Form. Please download the Clinical Trials – WVCTSI Form from the WVCTSI website and complete using the built-in instructions.

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

2) The NIH PHS 398 Inclusion Enrollment Report, to be downloaded from the WVCTSI website and completed 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) and the NIH PHS 398 Budget for Entire Proposed Project Period (Form Page 5). For this RFA, the budget is limited to a

maximum of $50,000 in total direct costs with a performance period of **twenty four (24) 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**

o 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.

o Funding is not available for student stipends for thesis or dissertation projects.
o Funding will not be awarded as bridge funding for ongoing, competitive projects.
o 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.*
***Specific CITI certificates are required for human studies. Non-clinical trial studies must include certificates from the "Human Research" curriculum group (ex: Biomedical Research Investigators). Studies categorized as clinical trials per NIH must include the CITI Good Clinical Practice (GCP) module. See NIH clinical trial criteria here.**

Note that the project's PI MUST be a WVU researcher with an active WVUCI membership. WVU faculty outside of the WVUCI and researchers with appointments at non-WVU institutions are permitted as co-investigators only. Those team members are also required to provide the appropriate compliance documentation.

- **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 Researchers:** Certification of CITI training, or equivalent, 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) 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.

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

5) 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.
6) Any application that meets the guidelines of a resubmission should include a one page response to previous reviewer comments.

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

11. Review and Selection Process

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. 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.

- **Significance**
- **Investigator(s)**
- **Innovation**
- **Approach**
- **Environment**
- **External Competitiveness**

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: 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.
- Applications intended to stimulate innovation and commercialization.

12. Award Notices: The formal notification in the form of a Notice of Grant Award (NGA) will be provided to the applicant via email for successful applications. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NGA are at the recipient's risk.

13. Reporting: Co-PIs that receive a WVCTSI Pilot Award will be required to submit a progress report every six (6) 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).

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.

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".
4. 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 be glad to assist you!

Contact	Phone Number	Email
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