Clinical and Translational Launch Pilot Grants Program
Request for Applications - 2016 Funding Cycle

Part 1. Overview Information

Proposal Due Date

- **June 6, 2016 by 5:00 PM EST**

Funding Opportunity Purpose
The goal of this Request for Applications (RFA) is to accelerate the translation of intellectual property developed by West Virginia University (WVU) researchers as well West Virginia Clinical Science Institute (WVCTSI) partner organizations into realized inventions as well as patents. Researchers should submit an application that meets the following criteria:

- 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 6-9 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- Project has progressed to the point where typical academic research funding sources are no longer applicable but the project has yet to reach a commercial value inflection point; and,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.

Budget
For this funding cycle, the budget is limited to a maximum of $50,000 in total direct costs with a period of performance of six (6) months.

Compliance Requirements
Researchers submitting a full proposal in response to this Launch Pilot Grant RFA must include CITI certification for investigators conducting research with human subjects as well as documentation of IRB protocol submission and/or IACUC protocol submission. Documentation for these requirements should be included in the Appendix of the application. IRB and IACUC approval is not required prior to application submission deadline, but must be completed within 30 days of project awards.

Repetitive Funding
Applicants who have received one of the following grants on the same general area of investigation within the last 12 months prior to application deadline from the following WVU internal funding mechanisms are not encouraged to apply: Bridge Funding, Research Funding Development Grant (RFDG), WVCTSI Funding, or PSCoR (Program to Stimulate Competitive Research).

Those with questions related to the funding restrictions may contact Dr. Anne Bolyard via email aebolyard@hsc.wvu.edu with any questions or concerns.

Part 2. Full Text of 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 WVU researchers to the market.

Other Requirements for the Launch Pilot Grants Program

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 cancer, neuroscience, obesity and metabolic disease, cardiovascular disease, stroke 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. An ESI is 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. For WVCTSI purposes, qualifying ESIs must have at least one year of eligibility remaining that meets the NIH definition of an ESI upon completion of their WVCTSI funded project. Junior Investigators and ESIs must identify a mentor to assist with the investigator's training with written documentation that the mentor is willing to serve in this capacity as well as a description of the mentoring team, if applicable.
- Applications intended to stimulate innovation and commercialization.

Section II. Application Guidance

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:

- Cancer
- Cardiovascular Disease
- Emerging Epidemics in Appalachia (Drug Abuse)
- Neuroscience
- Obesity and Metabolic Diseases

Application Types Allowed

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*.

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. There is not a limit on the number of resubmission applications to the Launch Pilot Grants Program under this RFA.

Award Project Period
The scope of the proposed project should determine the project period; the maximum project period is six (6) month; with the possibility of up to a three (3) month no-cost extension.

Section III. Eligibility Information
PI Eligibility is limited to the following:

- Faculty (all title series including regular, research, clinical) of the WVCTSI member institutions (West Virginia University, CAMC-Institute/WVU-Charleston, and West Virginia School of Osteopathic Medicine (WVSOM)) who intend to apply for external funding in the future.
- 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.
- WVCTSI Leadership are restricted from submitting applications which will direct funds into her or his program or lab.
- Individual PIs cannot receive WVCSTI funding for more than one Pilot Grants Program project. Upon completion of an initial Clinical and Translational Pilot Grants Program project, subsequent WVCTSI funding can be requested based on the PI's scholarly productivity relating to the initial funded project. Scholarly productivity includes the submission of applications for extramural grant opportunities, publications, and proceedings/presentations.

Additional Information on Eligibility

Restrictions
- Leaders of pilot projects must hold a faculty appointment or equivalent at the time the pilot award commences. 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 Project lead for Pilot projects may not concurrently have research funding from other IDeA Program award mechanisms (e.g. INBRE, COBRE).
- Pilot projects may not overlap with ongoing WVCTSI-funded projects.

Number of Applications
PIs can submit one full application by the submission date; but may be involved with other Launch Pilot applications as a Co-Investigator.

Section IV. Application and Submission Information
Format Specifications
Font restrictions: use a font size of 11 points or larger. The only acceptable fonts are the following: Arial, Helvetica, Palatino Linotype, or Georgia.

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 but it must be in a black font color, readily legible, and follow the font typeface requirement. Color can be used in figures; however, all text must be in a black font color, clear and legible.

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.

Page Limits: although many sections of your 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 and to contact WVCTSI Pilot personnel with questions prior to the submission of your Launch Pilot Grant application. Applications must be submitted via email as a single PDF document to Wesley Kimble (WKIMBLE1@hsc.wvu.edu) by the close of business (5:00 pm EST) on or before the deadline date. The application must include the following (please utilize the application templates referenced):

Face Page: please complete NIH PHS 398 Face Page (Form Page 1) and NIH PHS 398 Form Page 3. NIH Forms

Project Abstract: please use NIH PHS 398 Form Page 2; abstract length is limited by the text box. The abstract should describe: 1) the scientific research plan, 2) how the proposed project promotes clinical and translational research, and 3) how the proposed research supports one of the funding priority areas. NIH Forms

Approach/Research Plan: please use NIH PHS 398 Continuation Page. This section is limited to 5 pages and should include Specific Aims, Hypothesis, Background, Significance, Innovation, and Research Plan/Approach. Please use single space text. NIH Forms

- **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.
- **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. Cite published experimental details and provide the full reference in the Bibliography section. Given the length of the application,

investigators should strive to provide a relevant, although not exhaustive bibliographic review (described below):

(a) Hypothesis

- Clearly and briefly define the hypothesis of the project

(b) Background

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.

(c) 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 the commercialization milestones for the project, the plan and estimated timeline for achieving the milestones.

(d) Innovation

- Describe the state of the art compared to the proposed technology. Who is (are) the customer(s) for the proposed technology.
- 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.

(e) Approach

- Describe the potential impact the fully developed technology will have on clinical and translational research.
- 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.

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.

Human Subjects Protection Section: please use NIH PHS 398 Continuation Page (NIH Forms) and address all appropriate bulleted items below (no page limit):

- 4.1.1 Risks to Human Subjects
- 4.1.2 Adequacy of Protection Against Risks

- 4.1.3 Potential Benefits of the Proposed Research to Human Subjects and Others
- 4.1.4 Importance of the Knowledge to be Gained
- 4.1.5 Data and Safety Monitoring Plan (For Clinical Trials only)
- 4.2 Inclusion of Women and Minorities
- 4.4 Inclusion of Children

Budget
For all funding cycles, the budget is limited to a maximum of $50,000 in total direct costs with a performance period of six (6) months. Please use the NIH PHS 398 detailed budget form (Form Page 4); NIH Forms.

Allowable Costs
- Funds are to be used for the conduct of the project, including supplies, subject payments, assays, etc.
- Travel; travel to collect data or for collaboration purposes can be justified separately in the budget section.
- Equipment essential for the conduct of the study ($5000)
- Publication fees (not to exceed $1,000.00 per application)
- Data analysis costs
- Research assistant salary support
- 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

Unallowable Costs
- Funding for faculty salary support.
- 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.

Budget Justification

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.

Compliance Process
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.

Appendix

- Project timeline and milestones (include time for IRB approval process and subject/patient enrollment in the timeline).
- Outline of clinical protocol (if study is an investigator initiated clinical trial and not described in the proposal).
- A Biosketch in NIH Format (4 page maximum for each investigator from a WVCTSI member organization) must be submitted for all key research personnel. NIH Forms Be sure to include the following sections in the biosketch; Section A - Personal Statement; Section B – Positions held and honors received; Section C – Selected peer-reviewed publications; and Section D – Research support.
- Other support in NIH format (one for each investigator from a WVCTSI member organization, no page limit). NIH Forms.
- Documentation on regulatory approvals (CITI training for Protection of Human Subjects, Animal Assurances, etc. if applicable),
- Letters of Support for PIs from the partnering universities/agencies/organizations, if applicable. Endorsement (ESI and junior investigators): 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. It is NOT required that the mentor have funded effort.
- Mentoring and Career Development Plan (ESI and junior investigators): Please include mentor's information: Name, Degree(s), and Rank, Campus Address and Contact Information. Also include role and qualification of mentor(s). Inclusion of a clinician (physician, dentist, pharmacist, clinical psychologist, physical therapist, etc.) mentor is highly desirable in studies involving direct interaction with human participants. A career development plan must be in place to enhance clinical and translation research capabilities. This may include didactic coursework, the Clinical and Translational Science Seminar Series, and/or the Translational Science Spring/Fall Conference.
- 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.
- Letter from Supervisor/Department Chair: A letter signed by the immediate supervisor (e.g. Division Chief) and/or Department Chair that includes acknowledgement of their support for the project and providing assurance that sufficient protected time to complete the research will be available. No specific

amount of protected time is required, but the review committee will consider the distribution of effort and other activities of the applicant. Please include the name, email, and telephone number of Department Chair.

- Bibliography/References: Authors, year, title and journal information is expected for each citation. Given the length of the application, investigators should strive to provide a relevant, although not exhaustive review (no more than 2-3 pages).

Other Submission Requirements and Information
Prior to the deadline, please contact Wesley Kimble with any questions regarding the format of the application as well as other required aspects of the application. He can be reached at 304-581-1957 or via email at WKIMBLE1@hsc.wvu.edu.

The Launch Pilot Grants Program application package must be submitted as a single PDF document via email by 5:00 PM EST by the deadline date to Wesley Kimble at WKIMBLE1@hsc.wvu.edu. If the Launch Pilot Grants Program application package submitted by a PI does not meet all of the aforementioned requirements, the application will be returned to the PI without review and not considered for Launch Pilot Grants Program funding.

Section V. Application Review Information
Only the review criteria described below will be considered in the review process.

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).

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
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?

Investigator(s)
Are the PD(s)/PI(s), collaborators, and other PIs well-suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

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?

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?

Environment
Will the scientific 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 scientific 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, and in providing 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.

Inclusion of Women, Minorities, and Children
When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research.

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
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. University policy also requires training for personnel, which must be completed before a project utilizing radioactive material can start.
Any further questions pertaining to policy and procedures can be answered by referring to: http://www.hsc.wvu.edu/rsafety/.

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.

Review and Selection Process
As part of the scientific peer review, all applications:

- Will be assessed on the scientific and technical merit of the proposed project and relevance of the proposed project to outlined programmatic priorities.
- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.
- Will receive a written critique.

Final funding decisions will be made by WVCTSI leadership, as well as an advisory committee, 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.

Section VI. Award Administration Information
Award Notices
A formal notification in the form of a Notice of Grant Award (NGA) will be provided to the applicant for successful applications. The NGA signed by the PI as well as any other applicable individuals is the authorizing document. Awardees must comply with any funding restrictions described in *Section III*. 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.