The College of Medicine and Center for Health Services Research (in collaboration with the VPR, CCTS and UK HealthCare)

Call for Applications – Pilot Grants

Value of Innovation to Implementation Program (VI^{2}P)

The College of Medicine (COM) and the Center for Health Services Research (CHSR), in collaboration with the Vice President for Research, CCTS, and UK HealthCare is now accepting applications for grant funding of new research pilot projects focused on implementation/dissemination science that has high clinical value and impact. **This opportunity is open to eligible investigators from all UK Colleges.** Importantly, this funding mechanism is a clear step toward enhancing and leveraging our academic research and educational strengths to enhance clinical value and national impact through effective care delivery. We have great state-wide needs to address many health care challenges in Kentucky (e.g., Drug Addiction, High Cancer Mortality, Heart Disease, Stroke, Diabetes, Obesity, etc.) as well as national concerns over the inefficiencies in health care due to a lack of evidence based approaches to improve quality and efficiency. In fact, **the largest inefficiencies in health care as noted by the Institute of Medicine are the lack of use or implementation of known beneficial therapies** or use of unnecessary or non-evidenced based services that do not improve outcome, but come with associated risk and cost. As one example, thrombolytic drugs used for myocardial infarction with associated evidence of benefit and patient value, took approximately 13 years for sufficient clinical implementation (JAMA 268:240-248, 1992). Additionally, not only are academic medical centers the drivers of scientific evidence, but 40-50% of recommendations in standard of care guidelines are based on academic experts (JAMA 301:831-841, 2009). Therefore, the intent of this funding mechanism is to **leverage the research expertise in our Academic Medical Center to "leapfrog" the institution to greater healthcare value and impact through a transdisciplinary team approach, inclusive of clinicians** (e.g., physicians, nurses, pharmacists)**, implementation scientists, population and behavioral scientists, analysts, operations faculty and staff, and health care trainees—students, residents, and fellows.** Chosen teams will be expected to demonstrate methologically rigorous, generalizable, sustainable outcomes that have clinical impact and importantly, would be well positioned for future federal funding (NIH D&I research funding opportunity: https://grants.nih.gov/grants/guide/pa-files/PAR-16-238.html). To facilitate implementation science across the Health Care Colleges, the Health Care Enterprise and the Main Campus, we are launching the Value of Innovation to Implementation Program (**VI^{2}P,** https://chsr.med.uky.edu/vi2p) initiative as a pilot grant program with expert oversight and guidance (inclusive of an educational and mentoring program).

This funding mechanism provides a new opportunity and resources to support innovative, collaborative research projects that will identify, develop, test, evaluate and/or refine strategies to disseminate and implement evidence-based practices (e.g. quality improvement programs; diagnostic, treatment and disease management interventions; behavioral interventions; prevention, early detection) into public health, clinical practice, and community settings, developed by *a trans-disciplinary team, as well as the potential to include student, residents and fellows*. In addition, VI^{2}P encourages studies to advance dissemination and implementation research methods and measures or to de-implement clinical or community practices that are wasteful or not evidence-based but widely adopted.

Applications will be accepted and reviewed according to the following schedule

Call for Applications	Training Workshop** (Two Options)	Letter of Intent Due	Invitation to Submit Full Application	Full Application Due	Funding Decision
January 18, 2017	Feb 6, 11am – 1p / Feb 14, 10am - noon	March 23, 2017 (5:00 PM)	April 25, 2017	May 30, 2017 (5:00 PM)	July 11, 2017

** Mandatory

SCOPE AND PRIORITIES FOR FUNDING:

Dissemination and implementation research intends to bridge the gap between clinical research, everyday practice, and public health by building a knowledge base about how health information, interventions, and new clinical practices, guidelines and policies are transmitted and translated for health care service use in specific settings and public health. This RFP will support a variety of sound methodological approaches including observational, experimental, quasi-experimental, and simulation modeling approaches that produce relevant evidence on outcomes, costs, and/or unanticipated consequences. The goal is to conduct dissemination and implementation studies utilizing research designs that are both rigorous and relevant.

Dissemination research is the scientific study of targeted distribution of information and intervention materials to a specific clinical practice or public health audience. The intent is to understand how best to spread and sustain knowledge and the associated evidence-based interventions.

Implementation research is the scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings in order to improve patient outcomes and benefit population health.

Dissemination and Implementation (D&I) Research studies typically involve both interdisciplinary cooperation and trans-disciplinary collaboration, utilizing theories, empirical findings, and methods from a variety of fields not traditionally associated with health research (e.g., organizational and management theory, individual and systems-level behavioral change, business and public administration, anthropology, learning theory, engineering, marketing). D&I research often includes significant and ongoing collaboration with stakeholders from multiple public health and/or clinical practice settings as well as consumers of services and their families/social networks.

Within the general guidelines outlined above, the examples of relevant research studies that will be considered within this mechanism include:

- Strategies to implement health promotion, prevention, screening, early detection, and diagnostic interventions, as well as effective treatments, clinical procedures or guidelines into existing care systems.
- Local adaptation of evidence-based practices in the context of implementation that systematically identify intervention components that surpass or fall short of expected intervention effects.
- Patient-centered outcomes and cost-effectiveness of dissemination or implementation strategies to reduce health disparities and improve quality of care among rural, minority, low literacy and numeracy, and other underserved populations.
- De-implementation of clinical and community practices that are not evidence-based, have been prematurely widely adopted, yield sub-optimal benefits for patients, or are harmful or wasteful.
- Relationship of context and local capacity of clinical and community settings to adoption, implementation and sustainability of evidence-based practices.
- Influences on the creation, packaging, transmission and reception of valid health research knowledge.
- Systems interventions to impact organizational structure, climate, culture, and processes to enable dissemination and implementation of clinical/public health information and effective clinical/public health interventions.
- Development of D&I relevant outcome and process measures and suitable methodologies for dissemination and implementation approaches.
- Dissemination of varied strategies to promote effective patient and caregiver communication, leading to improved healthcare delivery and outcomes.
- Dissemination and implementation of effective and cost-effective strategies for incorporating genomic medicine, sequence-based diagnostics and therapeutics in clinical care.
- Testing the implementation and use of genomic information (e.g., Precision Medicine), family history risk information, and/or pharmacogenetic information for improved diagnosis and treatment.

ELIGIBILITY

Application will be open to all Faculty across the University inclusive of all Colleges and Centers. Investigators at all stages of career development, junior, middle level, and senior are eligible to apply.

- ***Eligibility is limited to full-time faculty (all title series including regular, research, clinical and special) at the University of Kentucky***
- ***Investigators in training including medical students, residents, post-doctoral fellows, and clinical fellows are NOT eligible to serve as PIs but are encouraged to be part of a proposed team and may be co-investigators.***
- ***Volunteer faculty and adjunct faculty are NOT eligible to serve as PIs but may be co-investigators.***

MANDATORY TRAINING WORKSHOP

All interested applicants who will serve as principal investigator or co-principal investigator are required to attend a 2-hour training workshop. As the dissemination and implementation research has progressed over the past decades, substantial advances continue in the development and application of D&I-related theories as well as innovative implementation strategies and methods. This workshop will build on participants' basic knowledge of D&I research. Subject matter experts from the Center for Health Services Research (CHSR) will address more complex issues of D&I study designs, theoretical and conceptual models, as well as the development and testing of D&I strategies. Workshop presenters will also describe common challenges and lessons learned while conducting D&I research activities. This seminar will include a mix of didactic presentation and group discussions.

This workshop will:

1) Deliver a brief overview of the field of D&I research and how it is applicable to learning healthcare organizations;
2) Engage participants in active learning about:
    a) Development of implementation strategies
    b) Measures and evaluation process of D&I research
    c) Selection and use of conceptual models and frameworks
    d) Design of D&I research

The required training workshop will be taking place on Monday, February 6 from 11am – 1pm at NURS Room 501C and, again, on Tuesday, February 14th from 10am – noon at NURS Room 115. To accommodate as many schedules as possible, we are holding the training at two different times. However, **please note that you only have to attend one or the other—not both**.

Workshop registration link: https://redcap.uky.edu/redcap/surveys/?s=YY8ET3PE8F

REVIEW PROCESS & CRITERIA:

Letters of Intent (LOIs) will be sent to a minimum of two internal or external reviewers with expertise in fields relevant to the science in the proposal. These reviewers will be asked to disclose any relationships to the grant applicant. LOIs will be subject to a standard NIH-type study section assessment. All LOIs will be scored based upon the written reviews, relevance to NIH scientific and technical merit and VI^2P priority criteria. All LOIs will be notified of the decision of full proposal invitation.

Complete applications, following invitation based on Letters of Intent, will be sent to a minimum of three internal or external reviewers with expertise in fields relevant to the science in the proposal. These reviewers will be asked to disclose any relationships to the grant applicant. Full proposals will be subject to a standard

NIH-type study section assessment. All applications will be scored based upon the written reviews, relevance to NIH scientific and technical merit and VI^{2}P priority criteria. The reviewers will then provide written feedback addressing the merits of the protocol. All applicants are **required** to attend a meeting with the CHSR VI^{2}P Review Committee to present an overview of their projects and address any questions from the committee. All applicants will be notified of the outcome.

VI^{2}P priority criteria

- Teams that includes at least one member with strongly funded science;
- A team that includes a clinician, a health data analyst, and an expert in quality improvement and process engineering;
- The likelihood that funding will result in submission of a competitive application for extramural funding including a trans-disciplinary team of scientists and practice stakeholders (Team Science);
- Projects with a clear plan toward future federal funding grant submissions;
- Clear description of feasibility and sustainability of implementation;
- Inclusion of students, residents and/or fellows;
- Relevance to the health challenges and disparities faced by the citizens of Kentucky.

General criteria

Overall Impact

Significance Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? What is the estimated health benefit of the research? Do the existing data, public health and patient needs justify dissemination and implementation? If the aims of the proposed project are achieved, how will dissemination and implementation knowledge be advanced? Will potential adopters and organizations be able to determine the applicability of the results to their setting?

Investigators Are the PI(s), collaborators, and other researchers well suited to the project? If the project is collaborative or multi-PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project? Is there clear evidence of dissemination and implementation research expertise as part of the team? Are the investigators part of stakeholder teams or have strong links and engagement of stakeholders necessary to accomplish the project aims?

Innovation Does the proposed dissemination or implementation research contribute new and innovative design approaches to the study of dissemination or implementation processes and/or outcomes? Do the methods proposed promise to speed the translation of research into practice and/or produce novel and robust findings?

Approach Does the applicant demonstrate an understanding of dissemination and implementation research principles? Is the dissemination or implementation approach appropriate to the problem and population using research methods that are relevant, rigorous and practical? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are the measures and analysis plan linked to the dissemination or implementation plan and study aims? How appropriate are the plans to sustain effective dissemination and implementation approaches once the research-funding period has ended?

Environment	Are the investigators capable of taking the results of the proposed study to scale to achieve public health impact? Is there evidence of institutional support to sustain dissemination or implementation interventions once the research funding ends?
Feasibility	Is the study feasible from the perspective of recruitment and availability of resources including a Dissemination and Implementation Research in Health feasible within time period proposed?
Potential	Will the pilot study generate new knowledge that can be published? Will completion of the study lead to generation of critical preliminary data and external funding?

FUNDING INFORMATION:

Individual project awards, up to $110,000 in total direct costs over an 18-month period, will be made on a competitive basis. Proposed costs should be commensurate with the work. Opportunities for second round of funding (renewal) will be considered based on progress.

Sufficient justification and detail should be provided to validate the need and cost of each item. The budget will be comprehensively reviewed to ensure that the funds being requested are relevant to the research being proposed.

ALLOWABLE COSTS:

- Funds are to be used for the conduct of the project, including supplies, devices, participant payments, etc.
- Non faculty personnel salary support*
- Travel funds that are needed for study conduct are allowed, if essential.

*To support collaborations including clinician scientists and to promote clinician-scientist's involvement in the proposed project, support for effort may be requested for a clinician scientist. For eligibility criteria, please refer to the " VI^{2}P priority criteria" noted above.

In the event that additional intra/extramural funds are secured to support the study outlined in your application you must immediately notify Shaunescia Davis at shaunescia.davis@uky.edu.

Funds will be held by the CCTS for the COM and the budgets invoiced for a period of 18 months maximum, dependent on the nature and scope of the study. Individual principal investigators will not be allowed to hold more than one CHSR pilot research award at any one time.

AWARDEE RESPONSIBILITIES:

- Once your protocol is fully approved and funding awarded, you should contact Lorin Franklin at lorin.franklin@uky.edu, to schedule a working meeting with the CHSR units involved with your protocol.

- Successful applicants will be required to provide semi-annual progress reports and attend face to face meetings with the CHSR "VI^{2}P Progress Committee". A final written report describing project accomplishments must be submitted **within 60 days** of the project end date.

RELEASE OF FUNDS:

- Funding for successful application will be released upon receipt of applicable IRB approval.
- If required IRB approval is not provided within a period of 30 days after the announcement of the award, **THE FUNDS WILL BE SUBJECT TO CANCELLATION.**

RESOURCES OF D&I RESEARCH:

The National Cancer Institute (NCI) Division of Cancer Control & Population Sciences webinar series
https://cyberseminar.cancercontrolplanet.org/implementationscience/

The National Implementation Research Network (part of the NIH) website
https://www.nlm.nih.gov/hsrinfo/implementation_science.html

The VA Health Services Research & Development on Implementation Science
http://www.hsrd.research.va.gov/research_topics/implementation_science.cfm

The VA Quality Enhancement Research Initiative (QUERI) http://www.queri.research.va.gov

AHRQ Dissemination Topic https://www.ahrq.gov/topics/topic-dissemination.html

University of Colorado Center for Research in Implementation Science and Prevention (CRISP)
http://www.ucdenver.edu/academics/colleges/medicalschool/programs/crisp/Pages/default.aspx

Writing Implementation Research Grand Proposals: Ten Key Ingredients
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3541090/

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VI^{2}P RESEARCH PROTOCOL SUBMISSION PROCESS

Letter of Intent (LOI) Submission and Review Information

The Pilot VI^{2}P research program supports discrete, well-defined trans-disciplinary Dissemination and Implementation Research in Health projects that can realistically be completed in eighteen months.

Letters of Intent (LOI) and Biosketches for Key Personnel in NIH format are required from applicants. The LOIs will be reviewed and subject to a standard NIH-type study section assessment by the CHSR VI^{2}P Review Committee, which is comprised of UK (and non-UK) faculty members with expertise in D&I research and study methodology. A subset of meritorious LOIs will be selected and applicants will be invited to submit full applications.

DEADLINE DATE for LOI: Thursday, March 23rd, 2017, by 5:00 PM local time.

Application Guidelines: The format of the LOI should follow the NIH guidelines outlined below.

- Margins must be no smaller than 0.5" at all points.
- Use an Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 11 points or larger. (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies).
- 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.
- EACH page should provide the applicant's name in the upper right hand corner. The application should be numbered consecutively in the center bottom.

The LOI Should be Assembled in the Following Order (limited to 2 pages):

1. Project Title (Full Project Title Required)

2. Research Objectives, Specific Aims – Provide concise, clear statements regarding statement of the problem, anticipated outcomes of the proposed research and how it will add to existing knowledge or create value

3. Brief Background and Pre-Data/Work if any

4. Paragraph describing Study Design, Methodology and Outcomes

5. Project Milestone(s)

6. Describe how the pilot project will facilitate a future external grant

LOIs must be submitted through the following link:
https://redcap.uky.edu/redcap/surveys/?s=HM3EMAF8D4

Paper applications will not be accepted.

Upon receipt, LOIs will be evaluated for completeness by the CHSR. LOIs that are incomplete or do not conform to stated guidelines will not be reviewed.

Full Application Submission Process

Based upon review of the LOI, successful investigators will be invited to submit a full application. Invited investigators are encouraged to contact Lorin Franklin at lorin.franklin@uky.edu, to schedule a meeting to review the basis of your submission, to learn how the VI^{2}P Initiative operates, and to learn which CHSR services you might utilize for your study.

We also suggest that you consult with the following individuals:

- For Study Design Consultation: Jing Li, MD, MS (jingli.tj@uky.edu)
- For Data Analytics Consultation: Dan Cleland, MS (dan.cleland@uky.edu)
- For Budgetary Consultation: Shaunescia Davis (shaunescia.davis@uky.edu)

DEADLINE DATE for FULL APPLICATION: Tuesday, May 30th, 2017, by 5:00 PM local time.

Application Guidelines:

Applicants are encouraged to review carefully the instructions provided below and to contact Lorin Franklin at 859-218-3943, lorin.franklin@uky.edu, with questions.

- ***Incomplete or incorrectly prepared applications will be returned without review.***
- ***All applications exceeding the requested page limit will be rejected and not reviewed.***
- References – Authors, year, title and journal information are expected for each citation. These **are not** included in the page limit and can be appended at the end of the body of the proposal.

The format of the full application should follow the NIH guidelines outlined below.

- Margins must be no smaller than 0.5" at all points.
- Use an Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 11 points or larger. (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies).
- 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.
- EACH page should provide the applicant's name in the upper right hand corner. The application should be numbered consecutively in the center bottom.

Your application should be submitted through the following link:
https://redcap.uky.edu/redcap/surveys/?s=4PK3CA77EA

Applications Should be Assembled in the Following Order

I. Detailed Budget and budget justification in NIH format, direct costs only

Proposed costs should be commensurate with the work. Sufficient justification and detail should be provided to validate the need and cost of each item. The budget will be comprehensively reviewed to ensure that the funds being requested are relevant to the research being proposed.
Allowable requests include:

- Devices essential for the conduct of the study
- Participant reimbursement costs
- Research assistant salary support
- Non faculty personnel salary support*

- Survey development and administration services
- Participant reimbursement/recruitment costs
- Travel funds needed for study conduct, if essential

*To support collaborations including clinician scientists and to promote clinician-scientist's involvement in the proposed project, support for effort may be requested for a clinician scientist. For eligibility criteria, please refer to the " VI^{2}P priority criteria" noted above.

Non-allowable Costs include:
- Funding is not available for thesis or dissertation projects.
- Funding will not be awarded as bridge funding for ongoing projects.

Applicants must account for fringe benefit costs when considering non-faculty research personnel salary levels.

NO INDIRECT COSTS ARE ASSIGNABLE THROUGH THIS MECHANISM.

Budget templates can be downloaded here: https://chsr.med.uky.edu/vi2p

II. Abstract and Partnership development (if applicable): (not included in the 6 page limit).

Abstract: The abstract should provide a brief (not more than 300 word) summary of the project. Beneath the abstract, each of the key personnel and their departmental affiliation should be noted. The key personnel should minimally include the PI(s), the designated mentor (applicable for new investigators, see below), and clinician/community health stakeholder(s). Data analytics and quality/process improvement consultants (if included), collaborating investigators and others may be listed, if they will play a significant, active role in the conduct of the proposed work. Key personnel listed should provide a letter confirming their role (INCLUDE THESE LETTERS IN THE APPENDIX).

An additional 300 words may be used to explain how this partnership will provide new opportunities for the investigators, any development activities that will be conducted throughout the project, and how these activities will build a sustainable infrastructure for an ongoing partnership.

III. Body of the proposal: (limited to 6 pages)

The format of the application follows NIH guidelines as outlined below.

Specific Aims (limited to 1 page, included in 6 page limit)
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 strategy/approach.

Research Strategy
Organize the Research Strategy in the specified order and using the instructions provided below. Start each section with the appropriate section heading—Significance, Innovation, Approach. Cite relevant published studies in the Research Strategy section 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.

(a) Significance

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Explain the estimated health benefit of the proposed project.
- Explain how the existing data, public health and patient needs justify dissemination and implementation.
- Explain how the proposed project will advance dissemination and implementation knowledge.
- Describe if and how potential adopters and/or organizations will be able to determine the applicability of the results to their setting.

(b) Innovation

- Explain how the proposed dissemination or implementation research contribute new and innovative design approaches to the study of dissemination or implementation processes and/or outcomes.
- Describe the promise/potentials of proposed methods of speeding the translation of research into practice and/or produce novel and robust findings.

(c) Approach

- Demonstrate an understanding of dissemination and implementation research principles.
- Discuss how the proposed dissemination or implementation approach is appropriate to the problem and population using research methods that are relevant, rigorous and practical.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- Describe the plans to sustain effective dissemination and implementation approaches once the research-funding period has ended.
- Discuss possible mechanisms of action, moderators, and mediators of dissemination and implementation strategies, if applicable
- Clearly describe how each partner will be engaged in the development and/or implementation of the proposed project. (Applicable for partnership applications)

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.*** Include information on Preliminary Studies. 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.

(d) Environment

- Explain the capability of taking the results of the proposed study to scale to achieve public health impact.
- Demonstrate the evidence of institutional support to sustain dissemination or implementation interventions once the research funding ends

IV. Appendix:

- Biosketch in NIH format

- Protection of human subjects section (if applicable)

- IRB approval letters or communications (if applicable)

- Bibliography - 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. (Not more than 5 pages)

- LETTER FROM PRIMARY MENTOR (New 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 MD, DO, PhD, PharmD or other doctoral degree and must have sufficient 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. This letter should be included in the appendix material of the application.

- 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.

- Letter (s) from all Key Personnel confirming their role in the project

- Relevant assessment materials may be included if they are of reasonable length and significantly enhance the review of the application. DO NOT submit published manuals, materials in the public domain or similar materials. This is NOT a means of extending the length of the proposal itself.