Pilot Grant Essentials

Pilot Projects Program

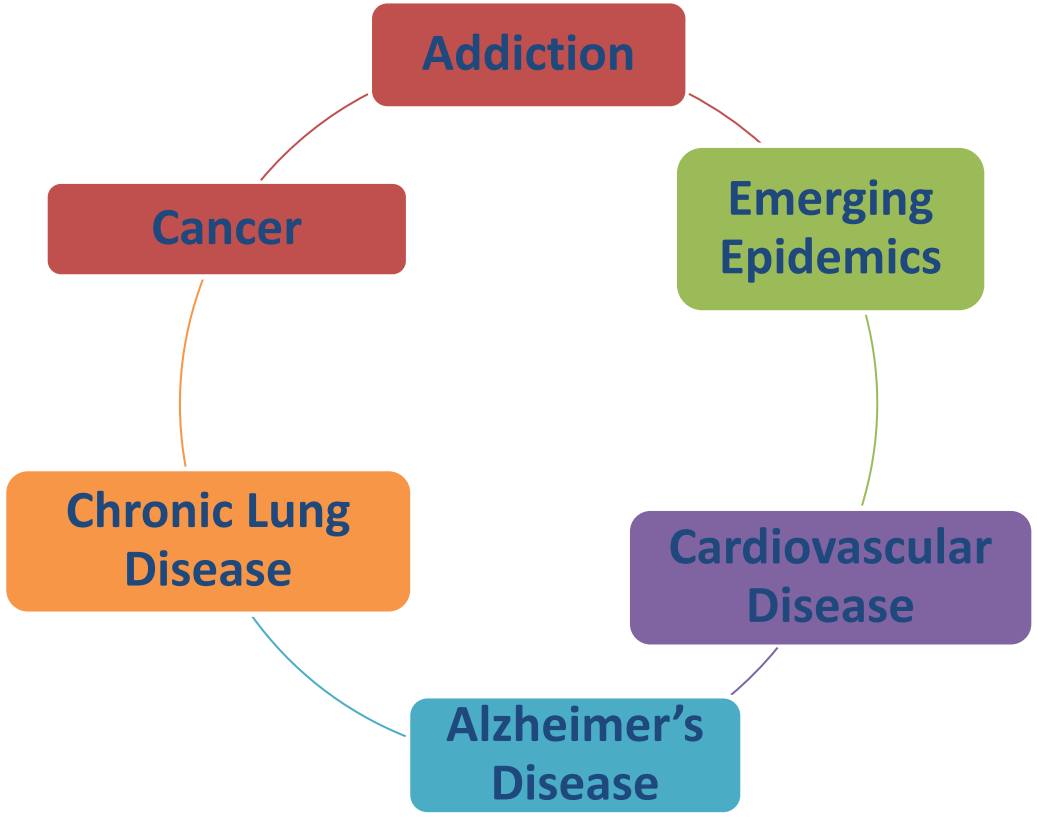
Meg Haller, MPA, MSW
Pilot Grant Coordinator
WVCTSI

WVCTSI Identity & Mission

- Funded by the National Institute of General Medical Sciences Clinical and Translational Research IDeA (CTR) Award.
- Establish crosscutting research partnerships among the WVCTSI partner institutions and our collaborating Clinical and Translational Science Award (CTSA) institutions to increase research capacity to improve the health of West Virginians and Appalachians.

WVCTSI Focus

- An academic home and a catalyst for clinical and translational research that targets priority health areas



Agenda

1. **Pilot Grant Program**
   - Eligibility, Budget, Application Process
2. **Tips**
3. **Additional WVCTSI Services**
4. **Q & A**

WVCTSI Pilot Grants

Funding Program	Detail	Amount	Duration	RFA Release
Open	Primary developmental funding opportunity for clinical and translational research.	$50,000	12/24	Once a year
Jumpstart	Obtain critical data needed to complete a manuscript submission or provide needed preliminary data for a grant application or resubmission.	$10,000	6	Twice a year
Launch	Provides proof of concept funding to accelerate the translation of intellectual property.	$50,000	9	Once a year
Rapid Response	Accelerate WVCTSI-supported research toward an emerging health issue.	$30,000	12	As needed
Bench-to-Bedside	Pair a basic scientist doing T0/T1 research with a clinical investigator.	$50,000 per year	24	Alternate years

Eligibility

- Not limited to WVU!
- Principal Investigators must hold a faculty/faculty equivalent position at one of the WVCTSI Partner Institutions
  - Charleston Area Medical Center (CAMC)
  - Marshall University *(must hold appt. in School of Medicine)*
  - West Virginia School of Osteopathic Medicine (WVSOM)
  - West Virginia University (all campuses)

CAMC Institute

MARSHALL

WEST VIRGINIA SCHOOL OF OSTEOPATHIC MEDICINE

WestVirginiaUniversity.

Available RFAs

RFA		Amount	Duration	LOI?
Open: Translational	The *Open Grant* is the primary developmental funding opportunity for clinical and translational research. These grants are investigator initiated and are particularly important for new and early-stage clinical scientists, supporting their unique and innovative research ideas, while serving as a mechanism for initiating and advancing their research programs.	$50,000	12	Yes, Due June 20
Open: Clinical		$50,000	24	Yes, Due June 20
Jumpstart	The *Jumpstart Grant* program is to allow WVCTSI researchers to obtain critical data needed to complete a manuscript submission or provide needed preliminary data for a grant application or resubmission.	$10,000	6	No, Full apps due July 11
Launch	The *Launch Grant* program provides proof of concept funding to accelerate the translation of intellectual property developed by investigators within the WVCTSI network.	$50,000	9	Yes, Due June 20

Available RFAs

Home | West Virginia Clinical & Translational Science Institute (wvctsi.org)

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

Appendices

Required for ALL projects

1. Biosketches for PI and Key Personnel (5 page limit per Biosketch)
2. CITI Certificates
3. Letter of Support
    - Chair or Center Director - Includes statement regarding time available for research endeavor *(PI - 10% recommended)*
    - Consultation from WVCTSI Service Cores

Appendices

AS NEEDED

- Human Subjects Protection Section & Completed Protocol
- Inclusion Enrollment Report
- Vertebrate Animal Section
- Proof of IACUC Submission
  - IRB/IACUC protocol title should match the proposal title
- Mentorship Agreement
  - Required for Early-Stage Investigators (ESI) serving as PI.
    - ESI within 10 years of terminal degree or professional residency/fellowship

Human Subjects

Last updated January 8, 2018
Form created by WVCTSI

Clinical Trials Template for WVCTSI Funded Projects

1.1 Study Title:

1.2 Is this study exempt from federal regulations? (y/n)
1.3 If Yes- Exemption number?

1.4.a Does this study involve human participants (y/n)?

1.4.b Are the participants prospectively assigned to an intervention (y/n)?

1.4.c Is the study designed to evaluate the effect of the *intervention* on the participants (y/n)?

1.4.d Is the effect that will be evaluated a health-related biomedical or behavioral outcome (y/n)?

An intervention is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies

If the answers to 1.4.a-1.4.d are all yes- this study qualifies as a clinical trial.

1.5 Provide the ClinicalTrials.gov Identifier if applicable:

ALL Human Subjects projects (including non-clinical trials) need to complete sections 2.1 to 2.8 and 3.1 to 3.2

2.1 Conditions or Focus of Study:

Enter up to 1500 characters

2.2 Eligibility Criteria

Enter up to 1500 characters

2.3 Age limits- minimum age: maximum age:
2.4 Inclusion of women, minorities, and children:

ALL PROJECTS

Answer the 4-question tree to determine whether your study qualifies as a Clinical Trial

- "No" at any point = NOT a Clinical Trial
- "Yes" to all 4 = Clinical Trial

Human Subjects

Last updated January 8, 2018
Form created by WVCTSI

Clinical Trials Template for WVCTSI Funded Projects

1.1 Study Title:

1.2 Is this study exempt from federal regulations? (y/n)
1.3 If Yes- Exemption number?

1.4.a Does this study involve human participants (y/n)?

1.4.b Are the participants prospectively assigned to an intervention (y/n)?

1.4.c Is the study designed to evaluate the effect of the *intervention* on the participants (y/n)?

1.4.d Is the effect that will be evaluated a health-related biomedical or behavioral outcome (y/n)?

An intervention is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

If the answers to 1.4.a-1.4.d are all yes- this study qualifies as a clinical trial.

1.5 Provide the ClinicalTrials.gov Identifier if applicable:

ALL Human Subjects projects (including non-clinical trials) need to complete sections 2.1 to 2.8 and 3.1 to 3.2

2.1 Conditions or Focus of Study:

Enter up to 1500 characters

2.2 Eligibility Criteria

Enter up to 1500 characters

2.3 Age limits- minimum age: maximum age:
2.4 Inclusion of women, minorities, and children:

ALL PROJECTS
Answer Sections
2.1 to 3.2

Last updated January 8, 2018
Form created by WVCTSI

Enter up to 5000 characters

2.5 Recruitment and Retention Plan

Enter up to 5000 characters

2.6 Recruitment Status (Not yet recruiting, recruiting, enrolling by invitation, active but not recruiting, completed, suspended, terminated, withdrawn):

2.7 Study Timeline:

2.8 Enrollment of first subject (anticipated or actual) date:

3.1 Protection of human subjects:

Enter up to 5000 characters

3.2 Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site (y/n)? If yes, describe the single IRB plan.

Sections 3.3 to 4.7 are for clinical trials only

3.3 Data safety monitoring pan

Enter up to 3000 characters

Budget

Allowable

- Non-Faculty Personnel Salary
- Materials, Supplies, Equipment
- Travel needed to complete study
- Publication Costs ($1,000)
- Conference Travel ($2,000)

Unallowable

- Faculty Salary (10% for PI on Open and Launch are allowable)
- Indirect Costs
- Student Stipends
- Bridge Funding

Funding Priorities

- ESI and/or Clinician Led Proposals
- Projects that utilize the PBRN or Community Engagement Strategies
- Partner institution PIs
- WVCTSI Thematic Research Priorities
  - Addiction
  - Emerging epidemics (ex: Hepatitis C, SARS-CoV-2, HIV)
  - Cancer
  - Cardiovascular Disease (including stroke)
  - Chronic Lung Disease
  - Alzheimer's Disease

Insider Tips

What Reviewers Look for

- Future Direction
  - External Application Plans
- Feasibility
- Consultations with WVCTSI Services
- Publication Track Record
- Appropriate Mentors
- Grantsmanship

Principal Investigator (PI) Academy Idea Lab

- PIs conducting clinical studies that plan on applying for a pilot grant are encouraged to present at an Idea Lab
- Receive feedback from our PI Academy panel of experts
- Please contact Debbie to set up an Idea Lab date and time. debbie.lee@hsc.wvu.edu

WVCTSI Core Services

Many services available to all partner institutions!

- Study Design and Biostatistics
- Biomedical Informatics Services
- Clinical Trials
- WV Practice-Based Research Network
- Telehealth (WVCTSI Project ECHO)
- Professional Development
- External Proposal Development

WVCTSI Cores & Services

Clinical Research Study Design, Epidemiology and Biostatistics (CRDEB)

GOAL

Ensure investigators have appropriate guidance, including research designs and data sets, to be successful in their research endeavors

Services

- Study Design
- Statistical analysis
- Bioinformatics
- Geographical Information Systems (GIS)

Biomedical Informatics Resources
1. Data request consults
2. Integrated Data Repository (IDR) ➢ Data from >1.5M patients
3. REDCap ➢ Web application for building and managing online surveys/databases for research
4. TriNetX

WVCTSI Cores & Services

Clinical Research Resources and Facilities (CRRF)

Goal

Provide services and expertise required to help investigators overcome the challenges of recruiting participants into clinical trials/studies.

Services

- Protocol development
- Study coordinators
  - Study execution
  - Consenting
- Regulatory support
  - IRB submissions
  - Training and Delegation documentation
- Regulatory Compliance

WVCTSI Cores & Services

❖ Professional Development

- ➢ Research seminars, Education (M.S., Ph.D., Certificate programs), Mentorship matching, Research Scholar Program, Interactive Grant Writing Groups, and INTRO Summer Research Program.

FACTS

Female **A**dvancing **C**linical and **T**ranslational **S**cience

- ➢ A professional development and networking group focused on empowering women conducting clinical and translational science.

WVCTSI Cores & Services

Community Engagement and Outreach (CEO)

GOALS

1. Provide single organizational structure for community members, healthcare providers, and researchers
2. Enable access to guidance, support, and technical assistance for community-engaged research to impact our state's health disparities

Services

- Connect investigators to community partners
- Community study design and implementation guidance
- West Virginia Practice Based Research Network
- WVCTSI Project ECHO

Resources

- Pilot Forms, Templates, and Resources
- Become a member!
- Pilot Grant Essentials YouTube Series
- PI Academy

Contact Information

Meg Haller, MPA, MSW
Pilot Grant Program Coordinator
mehaller@hsc.wvu.edu

www.wvctsi.org