Connecting with the WVCTSI
Overall WVCTSI Objectives

• Build sustainable research infrastructure that contributes to improving WV health outcomes.

• Recruit, train, and position for success the next generation of clinician scientists and translational researchers.

• Engage with multiple stakeholders, including communities, medical providers, and policy makers to drive research
Cross-Cutting Themes

① The “endangered” clinician scientist
   ➢ Train and support tomorrow’s clinician scientists, able to frame the right questions and work in teams to find answers

② Rural Populations
   ➢ Rural populations historically underrepresented in clinical research.
   ➢ Health concerns of individuals residing in rural communities are critical to WVCTSI mission

③ Commercialization
   ➢ Innovative strategies to maximize external investment and successful commercialization
Building the Infrastructure

- Increase research capacity through collaborations, recruitment, and training.
- Offers services that strengthen the quality of clinical and translational research.
- Engage communities in the research agenda.
WVCTSI ORGANIZATION
WVCTSI Partners and Practice-Based Research Network

CAMC / WVU Charleston
Marshall University
West Virginia School of Osteopathic Medicine
WV Veterans Affairs
National Institute for Occupational Safety and Health
West Virginia University
WVU Medicine
WVPBRN

West Virginia Clinical and Translational Science Institute
Health Priority Areas

- Addiction and resultant emerging epidemics
- Cancer
- Cardiovascular disease
- Chronic lung disease
- Neuroscience, including stroke & Alzheimer’s Disease
Professional Development

**Academic Programs in Clinical and Translational Science**

**Certificate Program** — one year didactic program; 15CH- ONLINE PROGRAM

**Master’s of Science Program** — 1-2 year didactic & experiential program; 34 CH
- Written grant proposal is a graduation requirement

**PhD Program** — 4-5 year didactic & experiential; Students complete semester-long research rotations in three domains: basic science, clinical, and population
Professional Development

Research Scholars Program – A program with the mission to support junior faculty to become independent clinical and translational investigators.

- Offers financial support, faculty mentoring, professional development seminars, and opportunities for the scholars to present their scientific work.

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

- An appointed steering committee meets quarterly to plan the professional development and networking opportunities.
- Hosts annual outreach events.

Workshops and Seminars – The Professional Development Core hosts Seminar Series and Workshops to address needs of faculty, fellows, residents, health professionals, and graduate students.

- Faculty development, grantsmanship, and mentoring are just a few of the topics covered during these professional development opportunities.
Proposal Development

Career Development (K-award) Grant Writing Club
- Provides guidance and advice to early-stage clinical and translational investigators planning to apply for a National Institutes of Health (NIH) Mentored Career Development Award
- Structured as a facilitated group writing process

Research Club (R-series) Grant Writing Club
- An intensive grant writing program for clinical and translational investigators developing R03/R21 applications for submission to the National Institutes of Health (NIH).
- Structured as a facilitated group writing process

Consulting and Coaching
- Dr. Joan M. Lakoski, Director of Proposal Development, offers individualized grant writing consultation and coaching through the Professional Development Core
# Pilot Projects Program

<table>
<thead>
<tr>
<th>Category</th>
<th>Grant Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small</td>
<td>• 5K for 6 months&lt;br&gt;<strong>Applications due September 7, 2020</strong></td>
</tr>
<tr>
<td>Collaborative</td>
<td>Closed</td>
</tr>
<tr>
<td>Launch</td>
<td>• 50K for 9 months&lt;br&gt;Focus on commercialization and technology development&lt;br&gt;<strong>LOIs Due August 3, 2020</strong></td>
</tr>
<tr>
<td>Open</td>
<td>• 50K for 12 months&lt;br&gt;Single PI&lt;br&gt;<strong>LOIs Due August 3, 2020</strong></td>
</tr>
</tbody>
</table>
Goals of the Clinical Trials Center of Excellence

1. Provide oversight infrastructure for all WVU HSC Clinical Trials
2. Assure regulatory compliance through institution of consistent training, audit and monitoring systems
3. Improve efficiency
Clinical Trials Center of Excellence

Provided Services
• Training
• Internal Quality Audit
• Regulatory Audit/Monitoring
• OnCore Clinical Trial Management

Optional Services
• Budget Development; Financial Management
• Regulatory Support – IRB Submission
• Study Coordination
• Recruitment Services
• Data Management; CRF Completion
• Communication liaison for IRB, sponsor, CRO

CTSI Clinical Trials
Cancer Institute
Heart & Vascular Institute
Rockefeller Neuroscience Institute
Pediatric Clinical Trials Group
Other Clinical Trial Groups
Benefits

All investigators receive:

- Centralized SOPs and templates for research conduct
- FDA or Sponsor audit readiness
- OnCore support
- Clinicaltrials.gov support
- Research personnel training
- Internal regulatory monitoring and auditing
- IND/IDE Support
- Improved contract efficiency (in partnership with Legal)
MISSION

The WVCTSI Principal Investigators (PI) Academy will:

• **Provide training** to investigators to enable them to be effective, efficient, and in compliance with both federal and local regulations

• **Serve as a catalyst** and home for investigators conducting clinical research as well as a central communication hub to disseminate training, policies, and best practices

• **Educate** investigators on their responsibilities as PI of a clinical trial

SCOPE

To provide WVCTSI-affiliated faculty researchers conducting clinical trials, as defined by the NIH, the appropriate infrastructure for successful trial conduct.

OPPORTUNITIES

• **Idea Lab** - PI Academy members can sign up to present their planned, current, or closing clinical trials to the group, and receive feedback from our PI Academy panel of experts. **Held the 1st Wednesday of every month 4-5pm.**

• **Relevant coursework** designed to suit your experience levels and needs. Earn a certificate via SOLE (free and self-paced).

• **Quarterly dinners with invited speakers** – During pandemic- moved to webinar format
WV Project ECHO Overview

Project ECHO is a lifelong learning and guided practice model that revolutionizes medical education and exponentially increases workforce capacity to provide best-practice specialty care and reduce health disparities. The heart of the ECHO model™ is its hub-and-spoke knowledge-sharing networks, led by expert teams who use multi-point video conferencing to conduct virtual clinics with community providers. In this way, primary care doctors, nurses, and other clinicians learn to provide excellent specialty care to patients in their own communities.

The WV Project ECHO program was developed and implemented in May 2016 through funding and support from the West Virginia Clinical & Translational Science Institute (WVCTSI), Claude Worthington Benedum Foundation, WVU School of Medicine, Cabin Creek Health Systems, Anthem, and The WV Primary Care Association in partnership with Project ECHO®.
WV Project ECHO Projects and Stats

Current WV Project ECHO Projects
- HCV/HIV
- Chronic Pain
- Medication-Assisted Treatment
- Psychiatry
- Chronic Lung Disease
- Endocrine
- Cardiac Health
- COVID-19

Current WV Project ECHO Stats
- WV Project ECHO currently has over 120 Spoke sites in WV and 10 surrounding states. WV Project ECHO also has had over 350 case presentations and over 4,700 attendees 819 which are unique attendees since its launch in May 2016.
Technology and Resources for Core Labs

Resources Available

• Inhalation Lab
• Genomics Shared Facilities
• State of the art imaging (MRI, EPR, etc)
• Microscope and Animal Imaging
• Flow Cytometry and Single Cell Analysis
• Electron Paramagnetic Resonance Imaging (EPRI)
TRCL: Biospecimen Repository

- Tissue Bank
  - Solid tissue may be collected prospectively per protocol needs, or researchers can access bank of stored samples
  - Sample processing and preparation also available
- Biospecimen Processing
  - On-demand collection of non-tissue biospecimens
Clinical Research Design, Epidemiology, and Biostatistics

- PhD-level statistical experts provide consultations on range of biostatistical and epidemiological services
- Data analysis, data management, sample size and power calculations, study design, spatial analysis
- Assistance with methods sections for manuscripts and presentations
Spatial Modeling and Analysis

- Spatial modeling services, cluster studies, and health services accessibility/capacity estimation
- Recent example: Modeling spatial variation in community level risk of fatal or non-fatal overdose and geographic access to prevention and treatment services
- Current project looking at instances of Congestive Heart Failure (CHF) in relation to patient proximity to active and non active coal mines.
Integrated Data Repository (IDR)

- Real-time copy of WVU Medicine electronic patient health record (EPIC) data on >1.5M patients
- Custom datasets can be created for research
- Highlights
  - Geocoding of addresses for geospatial analyses
  - Enhanced data security measures
  - Decedent data incorporated (NDI, & WV Vital Statistics)
  - Patient research registries with ongoing updates
COVID-19 Registry

- Custom-built registry containing information on everyone tested for COVID-19 in the WVU Medicine system
  - Nearly 30,000 patients
- Variables added based on investigator demand
  - ICU stays, ventilator usage, etc.
# TriNetX Global Health Research Network

## The Fastest Growing Global Health Research Network

<table>
<thead>
<tr>
<th>400M+</th>
<th>25</th>
<th>26,000+</th>
<th>7,000+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>Countries</td>
<td>Protocols Analyzed</td>
<td>Trials Presented</td>
</tr>
</tbody>
</table>

- Healthcare organizations, biopharma and contract research organizations collaborate to improve existing treatments & to expedite bringing new therapies to market.
- Members have access to:
  - Run queries across fully de-identified data from WVU Medicine (1.4M patients) or Research Network (~61M patients)
  - Explore feasibility, cohort characteristics and rate of arrival
  - Utilize Analytics feature for data insights

[https://live.trinetx.com/](https://live.trinetx.com/)
**TriNetX Global Health Research Network**

- Mechanism in place for re-identification of WVU Medicine patients with IRB approval for further research
- Upcoming enhancements include:
  - Diamond Network: patient linking to 3rd-party dataset with payer/claims, pharmaceutical data
  - Natural Language Processing: incorporate information from free-text notes into discrete fields
TriNetX Analytics

- Analyze outcomes over time or compare cohorts using measures of association, Kaplan-Meier survival analysis
- Easily balance cohorts with built-in propensity score matching
REDCap: Research Electronic Data Capture

- Secure, web-based application for data capture and storage
- Build and send surveys to participants, or enter data directly into a database
- User-friendly interface, data quality and protection measures, and audit trails
- Download data in formats suitable for all major statistical analysis software platforms

https://redcaplive.wvctsi.org/redcap
Agilent iLab

- iLab: streamlined service management system
- Comprehensive service request, tracking, and reporting capabilities
- All CTSI services should be requested via iLab
- Sign in with your WVU username and password to create an account

https://wvctsi.ilab.agilent.com
Benefits of Membership for Faculty, Clinicians, Associates and Trainees:

- Access to WVCTSI training and mentoring opportunities
- Access to research support services & resources such as the Integrated Data Repository & Biostatistics Consulting Services
- Information on clinical and translational research opportunities, including pilot funding

Click JOIN NOW on homepage or go to http://wvctsi.org/membership/
Thank you!

PARTNERING FOR BETTER HEALTH

WVCTSI
West Virginia Clinical and Translational Science Institute

@WVCTSI  Find us on  www.wvctsi.org