Rochester Early-Stage Investigator (RESIN) Program Workshop Series

Conducting Clinical and Translational Research – How CTSI Can Help

July 14, 2021
Rochester Early-Stage Investigator (RESIN) Program

The Rochester Early-Stage Investigator (RESIN) program works across departments and centers to optimize and support training for early-stage investigators from across the translational spectrum. We help early-stage investigators develop the skills and knowledge to innovate and improve the efficacy and efficiency of translation, from discovery to implementation and dissemination within the Learning Health System and beyond. By providing guidance and support, we aim to help you apply for and obtain career development grants.

RESIN is a collaborative effort among the UR CTSI, clinical and basic science departments and the Office for Faculty Development. Our activities complement, and do not replace, individual department and center efforts to support early-stage investigators. We also support the University's efforts to become a fully inclusive, equitable, anti-racist and multicultural organization by helping departments recruit and support diverse faculty.

Rochester Early Stage Investigator Network - Core Leadership Team
# Workshop Series

Starting in July 2021, RESIN will host a bimonthly workshop series covering a host of topics relevant to launching a research career. Workshops are alternately organized by the UR CTSI and the Junior Faculty Biomedical Research Association.

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Title and Presenter</th>
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| Wednesday, July 14, 2021 | Conducting Clinical and Translational Research: How the UR CTSI Can Help  
Presented by Carrie Dykes, Ph.D., Jeanne Holden-Wiltse, MPH, MBA, Edwin van Wijngaarden, Ph.D., of the UR CTSI. |
| September 2021  | How To Hire a Tech or Coordinator                                                  |
| November 2021   | How to Talk to a Biostatistician or Bioinformatician  
Presented by Michael McDermott, Ph.D., and Andrew McDavid, Ph.D. |
| January 2022    | Preparing and presenting an elevator speech                                         |
| March 2022      | Art of Writing a Good K Grant                                                     |
| May 2022        | Social media to maximize research exposure                                         |
| July 2022       | Networking retreat                                                                |
CTSI
ctsi.urmc.edu
Carrie Dykes
Director of Research Services
Research Help Desk Consultations

Identify resources relevant to your research
Identify collaborators
  • Internal and External
Perform funding searches
  • Governmental and Foundational
Identify previous NIH funded grants in your research area
Letters of support
Facility and Resources descriptions
COVID-19 resources

COVID Intent Form
• Complete for all COVID-related studies (new and modifications)
  • https://redcap.urmc.rochester.edu/redcap/surveys/?s=C7DPKWXEJX

Biobank
• Leftover serum from hospitalized COVID patients
• Plasma and cells collected prospectively

COVID research webpage, guidance for researchers website
• Has funding opportunities, guidance for labs, humans subjects research
  • https://www.urmc.rochester.edu/coronavirus/coronavirus-research/guidance-for-researchers.aspx

Facilities and Resources doc and reagent list
COVIDStudies.urmc.edu
What can I get from the CTSI?

Funding
Workforce Development
Informatics
Collaboration
Clinical Research
FUNDING
# CTSI Funding

<table>
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<tr>
<th>What</th>
<th>Who</th>
<th>When</th>
<th>Duration</th>
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<tr>
<td>Pilots</td>
<td>Faculty</td>
<td>Fall</td>
<td>1 year</td>
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<tr>
<td>Trainees</td>
<td>Fall</td>
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<td>UNYTE</td>
<td>Fall</td>
<td>1 year</td>
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<td>NBEM</td>
<td>Fall</td>
<td>1 year</td>
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<tr>
<td>Incubator</td>
<td>Sr. Faculty</td>
<td>Fall</td>
<td>2 years</td>
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<td>Pipeline to Pilots</td>
<td>Faculty</td>
<td>Varies</td>
<td>≤ 1 year</td>
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<tr>
<td>KL2</td>
<td>Jr. Faculty</td>
<td>Fall</td>
<td>2 years</td>
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Research Methods Forum

Interactive setting to present new or developing research ideas

Multidisciplinary experts who will provide recommendations

Similar to a NIH study section

In the first funding period

- 68 presenters, 12 in preparation, 24 submitted and 17 funded
- Total of $4.9 million
Collaboration
Community Engagement

The Center for Community Health & Prevention facilitates access to a range of consultation services related to community-engaged research. Services are offered to ensure that investigators have support for both project development and to conduct studies in the community.

Community engagement studios
Community-Based Participatory Research (CBPR)

Collaborative approach to research that involves community members Recognizes the unique strengths that each member of the research team brings.

Free course, sponsored by the UR CTSI and Center for Community Health & Prevention

Train University of Rochester researchers (faculty, trainees and students) and community members (typically from community-based organizations) in community-engaged research

Introduces CBPR principles from the

- Foundations
- Communication
- funding
- sustainability
- fosters relationship-building among participants.

Participants will form collaborative teams to develop and submit proposals for the CBPR Pipeline to Pilot Awards

Register by August 31, 2021
GR-PBRN

Greater Rochester Practice Based Research Network

147 member practices from primary care specialties and all local health systems
40 pediatric practices,
48 family medicine practices,
37 internal medicine practices
21 multi-specialty practices
350,000 adults (about 50% of Monroe County)
140,000 children (85% of Monroe County)
Clinical Research
Clinical Research
Office of Clinical Research
Participant Recruitment and Retention
Regulatory Support
Clinical Research Center
Trial Innovation Network
Office of Clinical Research

Implementing clinical research management system, OnCore

Finance service line
- Study budgets, financial management
- Participant payment system
  - Bank of America system ends Dec 31st

Feasibility
- Find studies for you
- Complete CDAs
- Complete feasibility surveys
Participant Recruitment

UR Health Research website- public website where people can search for ongoing studies and volunteer for future research

Participant registries
  • Local and ResearchMatch.org

Consultations- Advertising materials, Recruitment plans, Feasibility, Retention, Facebook advertising

Community Attitude Survey- data about our community’s attitudes and experience with research

Research Participant Perception Survey- survey your research subjects to get feedback

Health Research Advisory Committee- provides input to CTSI about institutional efforts around recruitment, looking for new members

Recruitment and Retention Course- offered through PHS
Regulatory Support

- Clinicaltrials.gov registration and results reporting
- Investigational New Drug (INDs)
- Investigational Device Exemptions (IDEs)
- Regulatory Science
- Pre-clinical studies
  - FDA GLP
Clinical Research Center

Located G-5000

- Nutrition Service
- Inpatient and outpatient
- Pediatric and Adult
- DXA
• 57+ CTSA institutions serving as a disease agnostic clinical trial network
• SMART IRB and master contract agreements
• Researchers can use the network by submitting a proposal for a study
• The CTSI will also be asked to find site investigators for studies coming from the network.
For More Information

Email: researchhelp@urmc.rochester.edu
Call: Research Help 275-2107
CTSI Data Services and Tools to Support Your Research

Jeanne Holden-Wiltse
Director of Informatics
Clinical & Translational Science Institute (CTSI)
Agenda

Tools and Data Services for
• Cohort Discover & Analytics
• Clinical Data Requests
• Data Management
• Biorepositories

Consultations

Summary of tools/resources
Informatics

The UR CTSI strives to create a research-friendly data environment that can help research teams maximize the impact of their clinical translational or basic biomedical research studies. Our expert Informatics team offers a variety of tools, services, and training to help researchers plan, access, analyze, and manage data for their studies.

Spotlight

COVID-19 Biobank Open for Business

The COVID-19 Biobank, created through a partnership between the UR CTSI and the Shared Resource Labs at the University of Rochester Medical Center, is now ready for use. University of Rochester researchers can request access to COVID-19 positive and negative blood specimens and associated, de-identified clinical data through the Biobank.

Research Data Management

Our experienced database developers, data managers, and statisticians offer a full range of data integration services for biomedical and translational research projects, including integration of clinical, specimen inventory and experimental.

Get a Free Consultation

The Informatics team can help you plan, access, analyze and manage data for your clinical, translational, or basic biomedical research studies. From planning and design to completion of your studies, our team has the tools and
Pre-study Phase

- Hypothesis generation - explore a hunch
- Determine if there are enough potentially eligible patients for your proposed study

Self-service clinical cohort discovery software tool to explore the URMC eRecord data for patient counts based on clinical criteria study inclusion and exclusion criteria
Cohort Discovery

TriNetX-LIVE

- User-friendly interface
- Data Domains
  - Demographics (HL7)
  - Diagnosis (ICD-9-CM/ICD-10-CM)
  - Medication orders (RxNorm)
  - Procedures (CPT-4/ICD-10-PCS/HCPCS)
  - Lab Results (LOINC)
  - Visit Types
- UR Medicine
  - Strong Memorial Hospital
  - Highland Hospital
  - FF Thompson Hospital
  - UR Medicine Ambulatory Clinics
  - URMC Urgent Care Centers
- Online training videos available
Cohort Discovery

- Returns number of patients for your cohort
- Explore cohort for distributions of patient characteristics
TriNetX Analytical Features - NEW

Let us know if you are interested in trying these new tools
TriNetX Other Networks - NEW

COVID-19 Research Network ~66M patients

Research Network ~61M patients

- Same cohort discovery and analytic functions
- Real-world evidence analysis
- Can request de-identified patient-level data from Research Network
Obtaining Patient-Specific eRecord Datasets

- Complete the service request form

- IRB approved protocol required for datasets containing PHI
Research Data Warehouse - Coming Soon

- Rapid deployment of “data marts” of EHR data and other data sources in a secure environment with appropriate analytical tools for researchers

- Access to additional EHR data domains, including notes
Data Capture & Management Solutions

Self-service, web application for building and managing online surveys and data collection forms

MyCAP - Capture participant reported outcomes using mobile devices

Links to a REDCap project
Data Capture & Management Solutions

Biospecimen software for vial labeling/printing, and specimen inventory and freezer management
Data management platform designed specifically to securely integrate and manage clinical/participant data with specimen inventory records and laboratory assay data (raw and processed) to support team collaboration.
Biorepositories

Project specific, customized integrations (including imaging)
BSI and BLIS

The Research Data Integration and Analytics team of the CTSI Informatics support research projects using BSI and BLIS via grant funding.

Anthony Corbett  
Alicia Tyrell  
Jennifer Dutra  
Zidian Xie  
Andrew Watts  
Sanjukta Bandyopadhaya  
TS Yeap  
Jeanne Holden-Wiltse  
Jeff Williams

UR Intellectual & Developmental Disabilities Research Center  
UR Vaccine Treatment & Evaluation Unit
Population Health Datasets

Interactive mapping and reporting tool of nationally representative data mapped locally by census track/zip code with ability to overlay multiple datasets and contribute datasets.

https://rochealthdata.org/
COVID-19 Resources

• **COVID-19 Data**
  • TriNetX Live for UR Medicine COVID-19 patients
  • TriNetX COVID-19 Network
  • **National COVID Cohort Collaborative (N3C)** - a centralized national COVID-19 data analytics platform to enable the rapid collection and analysis of clinical, laboratory and diagnostic data
    [https://covid.cd2h.org/](https://covid.cd2h.org/)

• **COVID-19 Biobank**
  • Leftover serum from hospitalized COVID patients
  • Plasma and cells collected prospectively
    [https://blis.urmc.rochester.edu/covid19/](https://blis.urmc.rochester.edu/covid19/)
Did you catch all that?
CTSI Informatics Consultations

Informatics team consultation can help you plan, access, analyze and manage data throughout the course of your studies. Whether you’re working with clinical, population health or basic biomedical data contact ResearchHelp@URMC.Rochester.edu
Summary of Data Tools/Resources

Self-service clinical cohort discovery and analysis tool to explore UR Medicine EHR data and broader network 62M patients for patient counts based on clinical criteria for hypothesis generation and study feasibility.

Self-service electronic data capture tool for participant data
redcapadmin@urmc.rochester.edu
REDCap eConsent guideline

Web-based biospecimen vial labeling and freezer management software*

Data integration and management system to store, visualize and securely share biomedical research, clinical, specimen and laboratory data*

Interactive mapping tool of nationally representative population-based data. https://rochealthdata.org/

* = fee for usage

More info: researchhelp@urmc.rochester.edu
CTSI Research Education

Edwin van Wijngaarden
Strategic Director of CTSI Research Education
Research Education & Workforce Development

The UR CTSI is dedicated to training the next generation of clinical and translational researchers. With educational programs tailored to pre- and post-doctoral students, faculty at all career stages and research staff, we have something for everyone. Our offerings range from certificate programs and week-long, intensive trainings to a fully accredited doctorate program. For questions or more information on our educational offerings, contact CTSI_education@urmc.rochester.edu.

PhD Program
Start a career dedicated to translating basic biomedical research into improved health in the Translational Biomedical Science PhD Program.

Research Methods Forum
Present new research ideas at this interactive forum to get feedback from multidisciplinary experts and potential collaborators.

Academic Research Track (ART)
Take a year out of medical school to conduct research with the guidance of mentor and optionally get formal training.

Learn about the PhD Program
Learn about the forum
Learn about ART

https://www.urmc.rochester.edu/clinical-translational-science-institute/education.aspx
Career Development KL2 Award

Provides two years of support for the early career development of multidisciplinary clinical and translational scientists

Fosters transition of KL2 scholars to an independent career as a clinical and translational investigator, generally by means of an individual K- or R-award

https://www.urmc.rochester.edu/clinical-translational-science-institute/funding/career-development-kl2.aspx
Career Development KL2 Award

Career Development Award scholars must:

• Define and participate in a clinical or translational research project
• Identify a multidisciplinary mentor team with extensive clinical or translational research experience where one of the members is willing to serve as the primary mentor
• Commit to a two-year program
• Devote at least 75 percent of their full-time professional effort to the program
Career Development KL2 Award

Letter of Intent typically due first week of October, with full proposal due one month later

Notification of recipients takes place in February, with July 1 start date of award

If you have additional questions about the program, please contact CTSI_Education@urmc.Rochester.edu
Academic Career Mentoring Consultation

**Goal:** to improve mentor-protégé relationship and ultimately increase the number of investigators who obtain mentored research career awards

**Educational workshops and mentor course:** designed to foster better mentoring skills by addressing common challenges such as giving feedback, diversity and cross-disciplinary mentoring.

**Finding a mentor:** Meet with a member of our mentor development committee for advice on where to find a mentor and how to build a mentor team.

**K-Award applications:** Early-stage faculty applying for mentored research career awards (K01, K08 or K23) can receive feedback on their mentoring plan, supporting letters, career goals and institutional environment with respect to career development activities.
CTSI Research Methods Forum

Provides an interactive setting for (human subject) investigators to present new and developing research ideas and receive feedback from an interdisciplinary team of experts

Held every 2nd and 4th Tuesday of the month, 2-3 pm

Present at an early stage of project development and return for follow up session

Written feedback is provided after the forum

Full proposal review is available to forum presenters

Please contact alaina_maiorano1@urmc.rochester.edu to schedule a session

https://www.urmc.rochester.edu/clinical-translational-science-institute/education/research-methods-forum.aspx
CTSI Research Methods Forum Team

Robert Strawderman, ScD
James McMahon, PhD
David Rich, ScD, MPH
Sally Thurston, PhD
Andrew McDavid, PhD

Edwin van Wijngaarden, PhD
Carrie Dykes, PhD
Kevin Fiscella, MD, MPH
Joan Adamo, PhD

Biostatistics
Bioinformatics
Clinical Trials
Dissemination & Implementation
Epidemiology
Recruitment & Retention
Regulatory Knowledge
Thank you so much for the feedback. It was an extremely valuable exercise and I think the feedback was excellent.

This has been invaluable to helping me refine my study and outcomes.

It was a really useful and informative meeting.

The forum by itself was a great opportunity, I really appreciate all the constructive criticism and all remarks, because it was an extremely valuable, awakening experience.

Thank you very much for the opportunity to present! The forum was very helpful, and we appreciate the extremely thorough feedback.
CTSI Research Education Hub

UR CTSI Research Education Hub

Find a host of learning modules, developed and curated by the UR CTSI, on Black Board. These modules provide professionals and trainees across the translational research spectrum with an overview of the key considerations in the design and conduct of clinical and population health studies.

Faculty who are preparing to present at the Research Methods Forum are encouraged to review these resources as relevant so that they can effectively discuss their goals, methods, issues and limitations regarding study design, recruitment, funding, and beyond.

How to Access the Hub

1. Log in to learn.rochester.edu using your NET ID.
2. Click the Courses tab on the top menu bar.
3. If you are already enrolled, the UR CTSI Research Education Hub will be listed in your Course List. Select to access.

*If the UR CTSI Research Education Hub is not listed, follow these steps*

4. Use the Course Search function to search for “Education Hub.”
5. Enroll in the course using the Course ID drop down menu.
6. The UR CTSI Research Education Hub should now be listed in your Course List.

Questions? Email CTSI_Education@urmc.rochester.edu.
### CTSI Research Education Hub Modules

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<td>Clinical Trials</td>
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<td>Epidemiology &amp; Research Design</td>
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<td>Team Science</td>
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**Content Area**

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<td>Dissemination &amp; Implementation Science</td>
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<td>Scientific Writing</td>
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**Epidemiology and Research Design**

This module contains a variety of videos and website links providing useful resources about the clinical research process and epidemiological principles.

- The Research Process
- Developing a Research Question
- Study Planning
- Epidemiologic Study Designs
- Confounding
- Effect Modification

For more in-depth coverage of these and related materials, please consider the following URMC graduate courses:

- PM415 Principles of Epidemiology
- PM413 Field Methods in Epidemiology
- PM416 Advanced Epidemiologic Methods

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**Clinical Trials**

This module contains a variety of videos and website links providing useful resources about clinical trials.

- Overview of key features of randomized controlled trials
- Issues in randomization
- Intention to treat
- Stepped-wedge designs
- Non-Inferiority trials
- Overview of adaptive clinical trial design
- Pragmatic trials

For more in-depth coverage of these and related materials, please consider the following URMC graduate course:

- BST465 Design of Clinical Trials
Rigor and Reproducibility
This module contains a variety of videos and website links providing useful resources about protocol development in clinical and translational research.

- UR Human Subject protocol templates
- NIH video on protocol development
- NIH Rigor and Reproducibility Training Modules and Webinars

The CTSI Office of Regulatory Support (ORS) offers services to support investigators with the navigation of and compliance with a range of governing requirements. In addition to general assistance with requirements as they arise, expertise is provided to support specific FDA-regulated processes, including research involving experimental drugs and devices, as well as preclinical laboratory studies. For more information: https://www.urmc.rochester.edu/clinical-translational-science-institute/clinical-research/regulatory-support.aspx

Leadership and Management
This module contains a variety of videos and website links providing useful resources about starting your own lab, and leadership and management in academia.

- Three Keys to Starting Your Own Lab (from "AAAS Letters to Young Scientists")
- The Secret to Giving Great Feedback
- Leadership and Management as a Scientist (from "Webinars for the NIGMS Training Community")
- Starting Your Own Lab (from "Webinars for the NIGMS Training Community")
- The Science of Effective Mentoring in STEMM (National Academies podcast)

Grantsmanship
This module contains a variety of videos and website links providing useful resources about NIH grant submission.

- Overview of NIH Grants Submission (video and website)
- Developing a Successful Research Career: What Type of Grant to Submit (video)
- Application Advice for Research Career Development (K) Awards (website)
- Writing an Effective "K" Application
- R01 Grants: Navigating NIH Peer Review (video)
- Grant Writing Tips (video)
- "Live" mock study section (video)
- Inside NIH Study Sections and Common Mistakes Seen on Applications (video)
- UR CTSI Seminar Series: Examples of Lessons Learned in Grant Writing (links to videos)
Public Health Sciences Graduate Programs

Ph.D. Programs
- PhD in Health Services Research and Policy
- PhD in Epidemiology
- MD/PhD Program

Master’s Programs
- Master of Public Health (MPH) Online or Online/On-Campus Hybrid - accredited by the Council on Education for Public Health
  - Master of Science in Clinical Investigation (MS-CI)
  - Master of Science in Epidemiology (MS-EPI)
  - Master of Science in Health Services Research and Policy (MS-HSRP)

Residency
- Preventive Medicine Residency

Certificate Programs
- Advanced Certificate in Analytic Epidemiology
- Advanced Certificate in Health Services Research
- Advanced Certificate in Clinical Research Methods Online
- Advanced Certificate in Experimental Therapeutics
- Advanced Certificate in Public Health Online
- Advanced Certificate in Regulatory Science
- Advanced Certificate in Biomedical Data Science
CLIC Education & Career Development Gateway

The CLIC Research Education Team mission is to empower and support a CTSA cooperative learning and training community that is inclusive and collaborative, facilitating and amplifying opportunities for the sharing of learning resources consortium-wide. We accomplish this through ongoing direct engagement with CTSA Program hubs, enterprise committees, working groups and individuals.

CLIC Education Clearinghouse

The CLIC Education Clearinghouse is a centralized space where the CTSA community can find and share a variety of education and translational workforce development resources from the CTSA consortium, searchable by learning domains, tags (keywords), target learners, and more. Each entry presents a detailed profile of the resource so that users can efficiently choose a resource that's right for them.

CLIC Career Development Community

The CLIC Career Development Community is an interactive space available to the CTSA Program and greater translational science community where individuals can collaborate, network, and share ideas with their peers from across the consortium. Each Focus Area includes a message board, highlighted content section, and searchable user list to foster communication, networking, and collaboration.

CLIC Opportunities Board

The CLIC Opportunities Board is the go-to resource for members of the translational science community, both within the CTSA Program network and beyond, looking to find (and post) jobs, training opportunities, internships, and Sabbaticals relevant to the world of translational science.

CLIC Education and Training Navigator

Request specialized help or guidance from the CLIC Education team to identify education and training resources, develop program activities, or locate potential opportunities for education and training synergies with other CTSA hubs.

https://clic-ctsa.org/education-careers
Education Clearinghouse

The CLIC Education Clearinghouse is a centralized space where the CTSA community can find and share a variety of education and workforce development resources for a broad range of audiences, from the general public to Principal Investigators. Curated lists of resources with a particular focus, call Resource Kits, can also be found here. Users can select and filter through a number of different areas: learning domains, tags (keywords), target learners, and more.

https://clic-ctsa.org/education/start
UNIVERSITY OF ROCHESTER MEDICAL CENTER

CTSI
CLINICAL & TRANSLATIONAL SCIENCE INSTITUTE

MEDICINE OF THE HIGHEST ORDER