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INSTITUTE FOR CLINICAL & TRANSLATIONAL RESEARCH

UMB Institute *for* Clinical & Translational Research
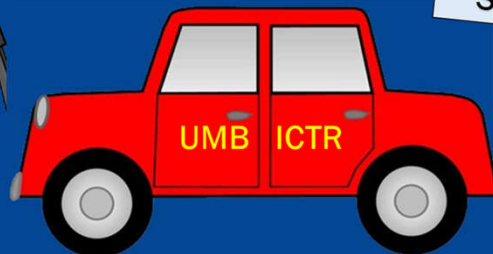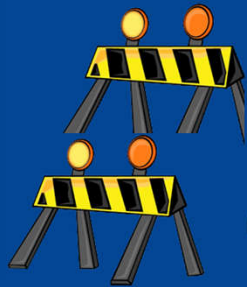
April 5, 2018

www.umaryland.edu/ICTR

UMB ICTR (ik-ter)

1st

Universitywide, interdisciplinary hub for clinical translational research and training, bringing together the schools of …

School of Dentistry

Carey School of Law

School of Medicine

School of Nursing

School of Social Work

School of Pharmacy

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Removing barriers to clinical and translational research and providing a supportive environment and high-quality resources…

Informatics
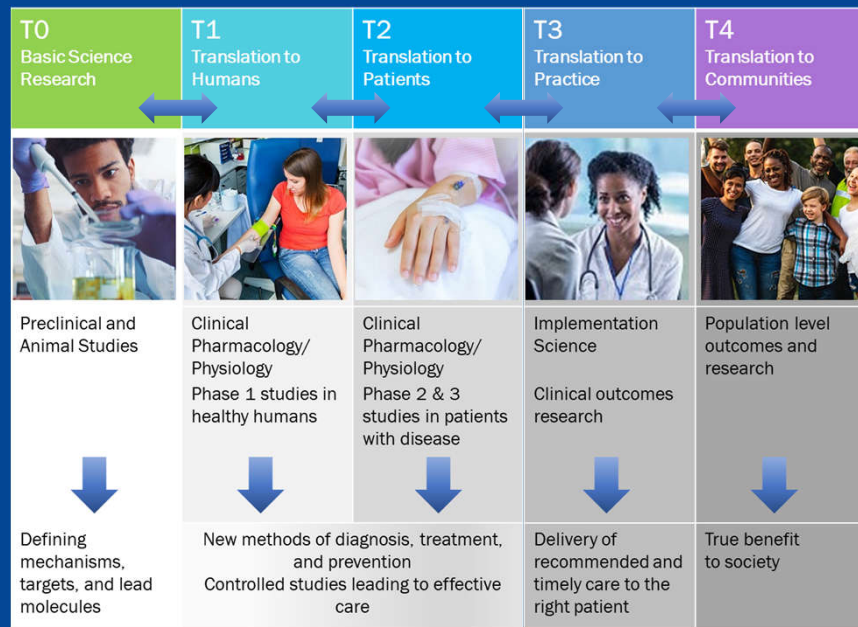Clinical Research Services
UMB Core Services
Community Engagement Expertise
Biostatistics
Pilot Funding
Mentorship
Experts on Ethics and Regulatory Science

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Translational Science Spectrum (T0-T4)

T0 Basic Science Research	T1 Translation to Humans	T2 Translation to Patients	T3 Translation to Practice	T4 Translation to Communities
Preclinical and Animal Studies	Clinical Pharmacology/ Physiology Phase 1 studies in healthy humans	Clinical Pharmacology/ Physiology Phase 2 & 3 studies in patients with disease	Implementation Science Clinical outcomes research	Population level outcomes and research
Defining mechanisms, targets, and lead molecules	New methods of diagnosis, treatment, and prevention Controlled studies leading to effective care		Delivery of recommended and timely care to the right patient	True benefit to society

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UMB ICTR is disease agnostic, supporting multiple endeavors to support health across diverse communities and the entire lifespan.
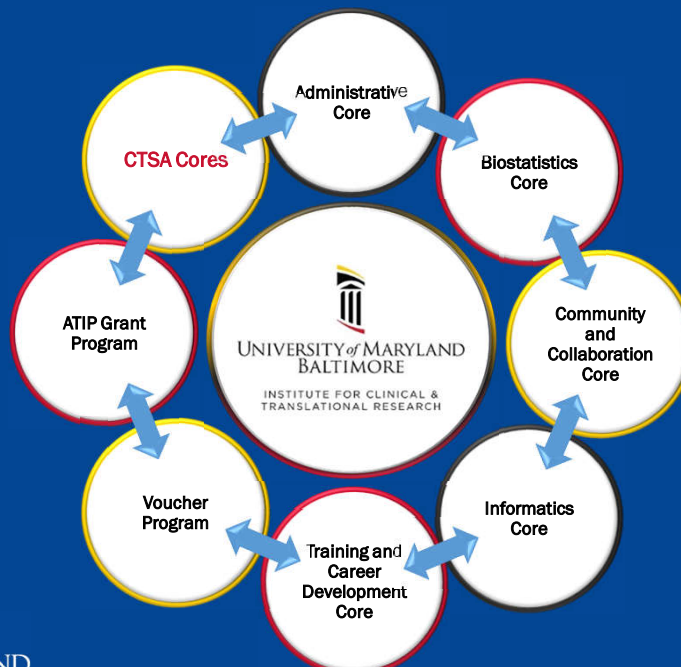

UMB ICTR Cores & Resources

Administrative Core
CTSA Cores
Biostatistics Core
ATIP Grant Program
Community and Collaboration Core
Voucher Program
Informatics Core
Training and Career Development Core

ICTR Biostatistics Core Leadership

Soren Bentzen, PhD, DMsc
School of Medicine
Director, ICTR Biostatistics Core

Laurence S. Magder, PhD
School of Medicine
Associate Director, ICTR Biostatistics Core

Shijun Zhu, DrE, MS
School of Nursing
Associate Director, ICTR Biostatistics Core

Eberechukwu Onukwugha, PhD, MS
School of Pharmacy
Associate Director, ICTR Biostatistics Core

ICTR Biostatistics Core Services

- Formulation of Research Question
- Study Design Sample Size Calculation/Power Analysis
- Data Collection/Preparing Data for Analysis
- Data Analysis
- Interpretation of Results
- Reports and Publications
- Statistical Bioinformatics
- Access to Data from Outside Sources

ICTR Community & Collaboration Core

C. Daniel Mullins, PhD
School of Pharmacy
Director, ICTR Community and
Collaboration Core

Elizabeth Galik, PhD, CRNP, FAAN, FAANP
School of Nursing
Associate Director, ICTR Community and
Collaboration Core

Thomas W. Oates, DMD, PhD
School of Dentistry
Associate Director, ICTR Community and
Collaboration Core

Fernando Wagner, MPH, ScD
School of Social Work
Associate Director, ICTR Community and
Collaboration Core

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ICTR Community & Collaboration Core Services

- Consultations with PATIENTS Program Outreach and Partners to develop appropriate communications   strategy for recruitment materials and dissemination
- Creating focus group/interpreting results
- Developing participant instruction/recruitment videos
- Assembling advisory board
- Connecting with Citizen Scientists

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Community and Collaboration Core

Foster and facilitate community engagement and collaborative effort by providing access to expert patient- and community-centered services and resources, such as:

• E.g., Creating focus groups, participant instruction videos, and assembling an advisory board

Support and Expand researcher access to the **PAT**ient-centered **I**nvolvement in **E**valuating the effective**N**ess of **T**reatment**S** (**PATIENTS**) resources and expertise

• Supported by the NIH
• National registry database of volunteers wanting to participate in research
• Over 7,000 volunteers registered within a 50-mile radius of Baltimore

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ICTR Community Engagement Initiatives

Provide Research Vehicle for Community Outreach Projects and Research Studies

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UMB Community Engagement Highlights

UMB CURE
Scholars Program

Clinical Law Program
Carey School of Law

Community
Outreach
Services &
Promise
Heights
School of
Social Work

PROMISE
HEIGHTS

Brain Bee
School of Dentistry

6,000+
GOVERNOR'S WELLMOBILE
VISITS ANNUALLY

PATIENTS Engaged in Research
School of Pharmacy

Governor's Wellmobile
School of Nursing

UMB Community
Engagement Center

Mini-Med School
School of Medicine

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ICTR Informatics Core Leadership

J. Kathleen Tracy, PhD
School of Medicine
Director, ICTR Informatics Core

Eun-Shim Nahm, PhD, RN, FAAN
School of Nursing
Associate Director, ICTR Informatics Core

Fadia T. Shaya, PhD, MPH
School of Pharmacy
Associate Director, ICTR Informatics Core

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ICTR Informatics Core Services

- Research Harbor Resources
- REDCap Database/Survey Development Services
- Qualtrics Survey Services
- Access to Clinical Data and other Specialized Datasets
- Data Use Agreement (DUA) Support
- Quality Assurance/Control Services
- Pre-review of data for "fit" to proposed project and data readiness for analysis
- Expertise on informatics projects that include end-user experience and user interface

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ICTR Training and Career Development Core

Rose M. Viscardi, MD
School of Medicine
Core Co-Director

Susan Dorsey, PhD, RN, FAAN
School of Nursing
Core Co-Director

Wilbur H. Chen, MD, MS
School of Medicine
Co-Director, ICTR Studios

James D. Campbell, MD, MS
School of Medicine
Co-Director, ICTR Studios

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ICTR ATIP Grant Program

The **A**ccelerated **T**ranslational **I**ncubator **P**ilot (ATIP) Grant Program provides starter funds for projects specifically focused on innovative, **translational research** that involve faculty from the UMB Schools and collaborative partners

Innovative Collaboration Pilot Grant	Community-Engaged Research Pilot Grant
• 4 or more awards • 12 months of funding up to **$50K**	• 1 award or more • 12 months of funding up to **$50K**

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ICTR Voucher Program*

Gloria Reeves, MD
School of Medicine
Co-Director, ICTR Voucher Program

Thomas W. Oates, DMD, PhD
School of Dentistry
Co-Director, ICTR Voucher Program

To enable generation of data on clinical and translational research projects by defraying the costs of other UMB Core Services

* Priority will be given to IRB-approved ATIP grants, K awards, and all funded, externally peer-reviewed, clinical and translational research

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ICTR Voucher Program

Up to $10K in Voucher Support per Applicant

General Clinical Research Center (GCRC)
- Inpatient & Outpatient Unit; Open 24 hours a day, 7 days a week!
- Provides safe space and research nursing for clinical research studies
- Specimen collection & processing, study drug administration, DEXA machine, specialized procedures, i.e. biopsies, glucose clamps
- Research Subject Advocate
- Currently supports ~70 protocols per year, 85% federally-funded protocols
- Since 2011, GCRC has supported 230 active protocols, $139.8 M in grant awards

Center for Innovative Biomedical Resources (CIBR)
- The administrative home for the UMB biomedical core resources:
  - Cytometric and Bioassay facilities, i.e. Cytokine Laboratory
  - Clinical Resource Facilities, i.e. Translational Core, Cytogenetics
  - Imaging Technologies, i.e. Magnetic Resonance Research Center
  - Structural Biology Facilities, i.e. Mass Spectrometry, Protein Analysis

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ICTR Resources, continued

Studios
- The "Studios" program brings together multi-, interdisciplinary experts to provide free, structured, project-specific feedback for researchers

Ask The Navigator
- The ICTR Research Navigator is available to help direct investigators to ICTR services and other UMB core services, as needed, and to advise them on the "next steps" in their clinical and translational research projects

Mobile Research Van

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ICTR/CTSA Training Program

The overall goal of the Training and Career Development Program is to educate, train and develop future generations of clinical scientists needed to move basic research findings into novel therapies.

Training Award	# of Slots per year	Funding	Training Program Budget
TL1	5 (2 Pre-doc & 3 Post-doc)	12 months	$315,386 for 5 trainees per year Includes Stipend, Tuition & Fees, and Other expenses: Disability and Health Insurance, Travel to attend workshops/seminars
KL2	Year 1: 1 scholar Years 2-5: 2 scholars (Junior Faculty)	2 years (3rd year: cost-shared)	$517,260 per scholar Includes Salary support, fringe benefits, Other expenses: Travel, Tuition & Fees, and Research Funds

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2018 ICTR Resources

- Regulatory Knowledge & Support Advisors
- Centralized Training Grant Tracking Database
- Clinical Research Coordinator Training Program
- Integrating Special Populations
- Innovation/ Entrepreneurial Core
- Clinical Trial Management System (CTMS) for UMB
- Drug Discovery & Development

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ICTR Metrics of Success

- Retain & attract best students, scholars, trainees, & faculty regionally and nationally
- Elevate national scientific rankings of UMB schools
- Double NIH and extramural clinical and translational research funding
- Develop new treatments and technologies to combat and cure acute and chronic diseases
- 30% of UMB faculty (in collaboration with other UMD schools and/or JHU) using ICTR resources
- Double the number of Clinical and Translational Scientists trained at UMB
- Increase # of publications in top-tier, peer-reviewed clinical & translational scientific journals

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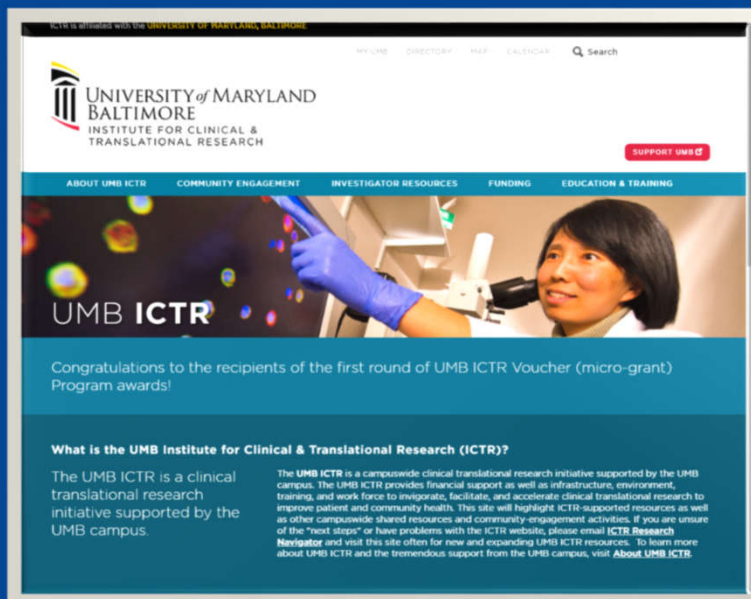INSTITUTE FOR CLINICAL & TRANSLATIONAL RESEARCH   23

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