UMB Institute *for* Clinical & Translational Research

September 30, 2020

www.umaryland.edu/ICTR

ICTR-Navigator@umaryland.edu

UMB ICTR

1st

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

Translational Science Spectrum (T0-T4)

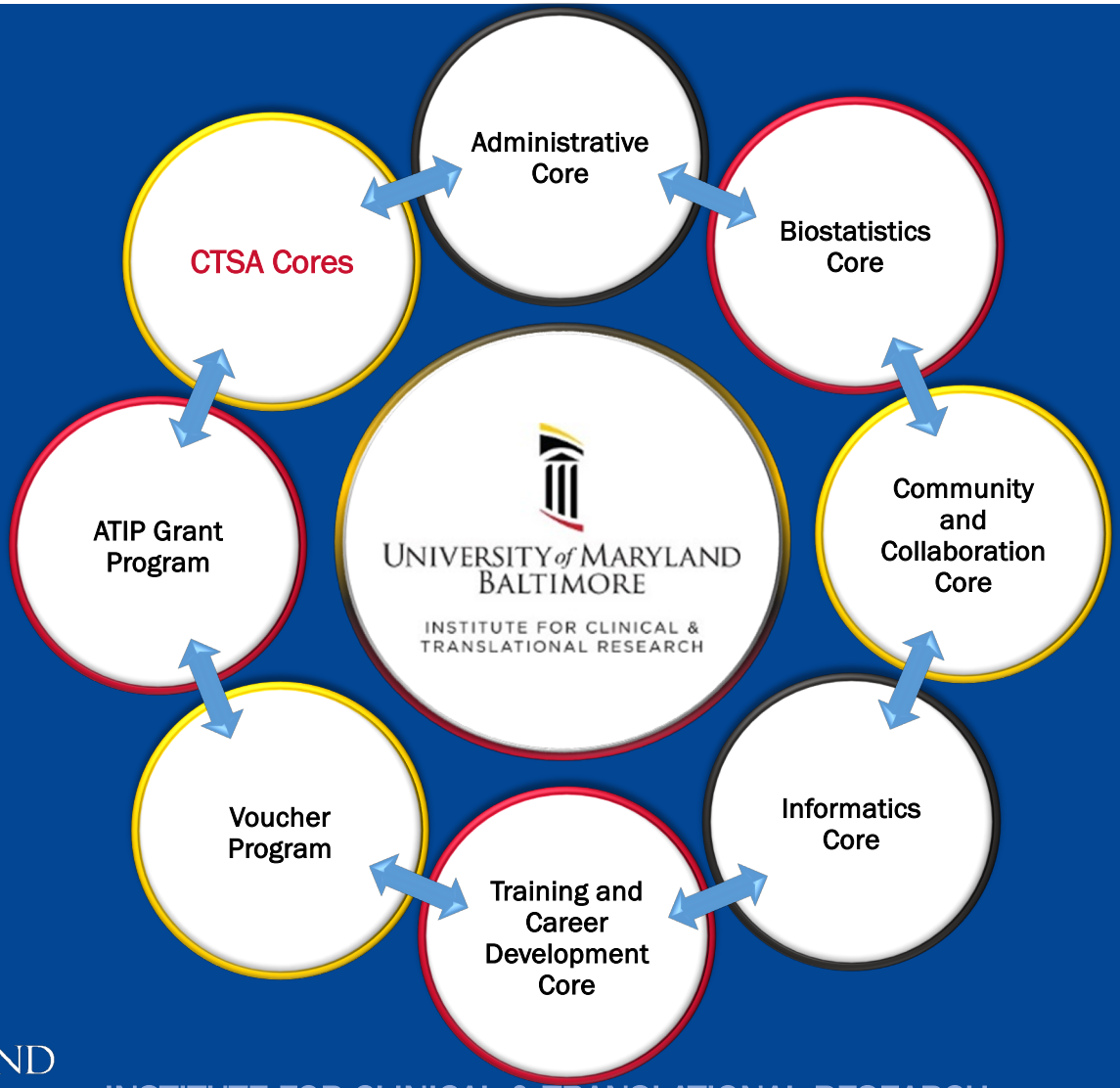
T0 Basic Science Research	T1 Translation to Humans	T2 Translation to Patients	T3 Translation to Practice	T4 Translation to Communities
Preclinical and Animal Studies	Clinical Pharmacology/ Physiology Phase 1 studies in healthy humans	Clinical Pharmacology/ Physiology Phase 2 & 3 studies in patients with 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

UNIVERSITY of MARYLAND BALTIMORE

INSTITUTE FOR CLINICAL & TRANSLATIONAL RESEARCH

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

UMB ICTR Cores & Resources



ICTR Biostatistical Core Services

Study Design and Power Analysis	• Feasibility study and sample size based on multistage and adaptive designs; Design and perform randomization; Data analysis plan
Access to Non-EHR Data and Data Use Agreements	• Access to Medicare and Claims Data and assistance with securing memorandums of understanding or data use agreements
Interim Analyses and Data and Safety Monitoring	• Analyses and adaptive designs (including Bayesian designs) consistent with statistical principles for multiple testing and interim analyses
Statistical Analysis	• Beyond major statistical software packages such as SAS, Splus, Stata, StatXact and East, more complex statistical and bioinformatics tool are developed for specific research project (in R or Matlab or SAS)
Statistical bioinformatics	• Analysis of "Big Data" including systems biology, gene regulatory network inference, module biomarker discovery, network biology, data integration, systems pharmacology, personalized medicine, disease-drug-gene association discovery, pattern recognition, image analysis, and data mining
Reports and Publications	• Data analysis is typically summarized in a statistical report in a form appropriate for manuscripts

ICTR Informatics Core Services

TriNetX and Research HARBOR	• Access to clinical EHR data in the UMMS system and soon across UMMS-JHU systems
REDCap	• Allows users to build and manage online surveys and databases quickly and securely
Qualtrics	• Leading enterprise survey company; Easy to create and distribute engaging surveys
Cybersecurity and AI core - UMBC	• Creating a new approach to data
Access to Non-EHR Data	• Claims and administrative data, through collaborations with the Pharmaceutical Research Computing Center and others
Implementation and Dissemination	• Identifying researchers barriers to approaching informatics and data science, and addressing the gap in the translation of evidence into practice, policy and programs.
Digital Health	• Real-time data collection from health related devices

ICTR Community & Collaboration Core Services

- Consultations with **PATIENTS Program** Outreach and Partners to develop appropriate communication strategies for recruitment materials and dissemination
- Creating **focus group**/interpreting results
- Developing participant **instruction/recruitment videos**
- Assembling **advisory board**
- Connecting with **Citizen Scientists**
- Assist with **writing community-engagement section** of your funding proposal

ICTR Community Engagement Initiatives

Provide Research Vehicle for Community Outreach Projects and Research Studies

Additional ICTR Resources

Ask The Navigator

- The ICTR Research Navigator directs investigators to ICTR services and other UMB core services and also advises on the “next steps” in their clinical and translational research projects.

Studios

- The “Studios” program brings together interdisciplinary experts from both **UMB** and **JHU** to provide structured, project-specific feedback for researchers

ResearchMatch

ICTR Funding Opportunities

Two Mechanisms:

- Voucher "micro grant' Program
  - Up to $5k in voucher support to enable generation of data on clinical and translational research projects by helping to defray the costs of other UMB Core Services
  - Applications accepted every 3 months. Next deadline November 2, 2020
- ATIP Grant Program
  - Up to $50k in direct cost
  - FOA announced in the Fall with application deadline November 13, 2020.

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, UMBC and collaborative partners

Innovative Collaboration Pilot Grant	Community-Engaged Research Pilot Grant	Cybersecurity, AI, Machine Learning
• 12 months of funding up to **$50K**	• 12 months of funding up to **$50K**	• 12 months of funding up to **$50K**

ICTR Core Services and Funding Stats*

Core Service Hours Approved		
Core	Requests	Approved Hours
Biostatistics	173	2819
Community Collaboration	31	861
Drug Discovery & Development*	29	495
Informatics	63	847
Studios	24	139
TOTAL	320	5161

Voucher Program Awards	
Requests	136
Projects Awarded	119
Total Support	$643,245

ATIP Grant Program			
Round	Apps	Funded	$$ Awarded
2020-COVID	41	10	$296,250
2020	35	17	$545,000
2019	36	19	$475,000
2018	25	12	$375,000
TOTAL	137	58	$1,691,250

*Dec 2017- Sep 2020 (D3 Core as of May 2019)

Distribution of voucher awards across UMB Cores

Core	Distribution of Vouchers	Amount
Biopolymer/Genomics Facility	5	$20,050
Bioresco	11	$29,884
Biosensor	1	$4,000
Confocal Microscopy	2	$6,240
Center for Biomolecular Therapeutics (CBT)	1	$5,000
Center for Translational Research in Imaging (CTRIM)	14	$82,950
Cytokine Core Lab	4	$17,434
Electron Microscopy Core Imaging	5	$20,570
Flow & Mass Cytometry	2	$7,500
Flow Cytometry Facility	5	$19,422
General Clinical Research Center (GCRC)	12	$77,322
Genomics Resource Center (IGS)	18	$92,859
Investigation Drug Services (IDS)	3	$19,184
Informatics Resource Center (IGS)	8	$50,000
NORC	2	$7,400
Pathology Biorepository (PBSS)	3	$7,399
PHSR Community Database (SOP)	3	$14,000
PPC Surgical Services	2	$13,800
PRC (SOP)	4	$19,620
Translational Core Lab	17	$76,135
UMM Bio Repository (Bio Bank)	2	$9,992
µQUANT Facility (IHV)	1	$4,675
Vet Services	4	$14,409
Community Engagement Vouchers	5	$24,100
TOTAL:	**134**	**$643,245**

Grant Applications supported by ICTR

Funding Agency	Total # of Applications	Direct Costs Requested	Indirect Costs Requested	# Awarded	Direct Costs Awarded	Indirect Costs Awarded	# In Review	Direct Costs Requested	Indirect Costs Requested
Foundation/Nonprofit	19	$10,944,232	$1,439,187	9	$4,152,626	$2,914,439	5	$5,751,428	$867,580
Industry	1	$150,261	$31,969				1	$150,261	$31,969
NIH	56	$96,449,471	$47,078,344	17	$34,102,528	$13,955,532	17	$21,196,484	$11,341,551
Other Federal Agency	8	$6,141,227	$1,228,291	2	[illegible]	$309,016	2	$1,880,481	$0
Grand Total	**84**	**$113,685,191**	**$49,777,791**	**28**	**$39,102,380**	**$17,178,987**	**25**	**$28,978,654**	**$12,241,100**

12/3/2017-9/29/2020

General Clinical Research Center (GCRC)

- The General Clinical Research Center (GCRC) provides University investigators a specialized research environment to conduct clinical research
  - Located in UMMC, South Hospital Building, 10th Floor, C & D Wings – 7,400 sq ft
    - One floor above the Investigational Drug Services (IDS)
  - Inpatient and Outpatient facility; two specimen processing laboratories- Open 24 hours, 7 days a week
  - Phase 1 Unit Expansion- To accommodate Phase I and IIa studies

What Resources Can The GCRC Provide?

- Research Nurses and support staff
- 24-hour nursing care, 7 days a week
- Clinical space
- Education and Training
- Regulatory support and guidance from our Nurse Manager
- EPIC software
- Off site visits

Nursing Staff

- RN's and PCT's with the education, certification and skills to provide quality research participant care. Including but not limited to:
  - Phlebotomy: single or serial PK's
  - Specimen Collection/Processing
  - Investigational Drug Administration
    - Chemotherapy Administration
  - Special Testing/Procedures- GFR, Muscle & Fat Biopsies
  - POC testing: Blood Glucose, Pregnancy Testing, Urinalysis, Hemacue/Hemoccult –CLIA certified
  - Subject Teaching
  - New services to include Chart Reviews and Data Entry

Investigator Support

- Consultation
  - Protocol development and review
- GCRC Advisory Committee (GAC)
  - Provides mentorship and guidance for new investigators
- Provide a safe and precise clinical environment for all forms of clinical research
- For more information, please contact:
  - Meghan Banchero, Administrative Director - mbanchero@som.umaryland.edu
  - Jennifer Marron, Nurse Manager - jmarron@som.umaryland.edu

Clinical & Translational Science Award- CTSA

The CTSA was funded with a start date of May 31st, 2019

Project Period: 5/31/2019 - 04/30/2024

UL1 : Johns Hopkins Institute for Clinical and Translational Research
KL2 : Institutional Career Development Core
TL1 : NRSA Training Core

ICTR/CTSA TL1Training Program

TL1 Training Award	# of New Slots	Length of Funding
CTSA PRE-doc	1 PRE-doc per year	12 months *Funded by CTSA*
ICTR PRE-doc	1 PRE-doc per year	12 months *Funded by ICTR*
CTSA POST-doc	2 POST-docs per year	2 years *Funded by CTSA*

ICTR/CTSA KL2 Career Development Program

Training Award	# of New Slots	Length of Funding
CTSA KL2	1 Junior Faculty per year	3 years *2 years CTSA and 1 year internal funding*
ICTR KL2	5 Junior Faculty every 3 years	3 years *3 years internal funding*

CTSA Brings Additional Cores

Drug Discovery and Development

- Pharmaceutical Manufacturing and Enabled Clinical Trial Formulations
- Pharmacometrics
- Computer-aided Drug Design
- Advanced Protein Characterization for Therapeutic Protein Development

Research Methods Core

- Regulatory Knowledge & Support Advisors

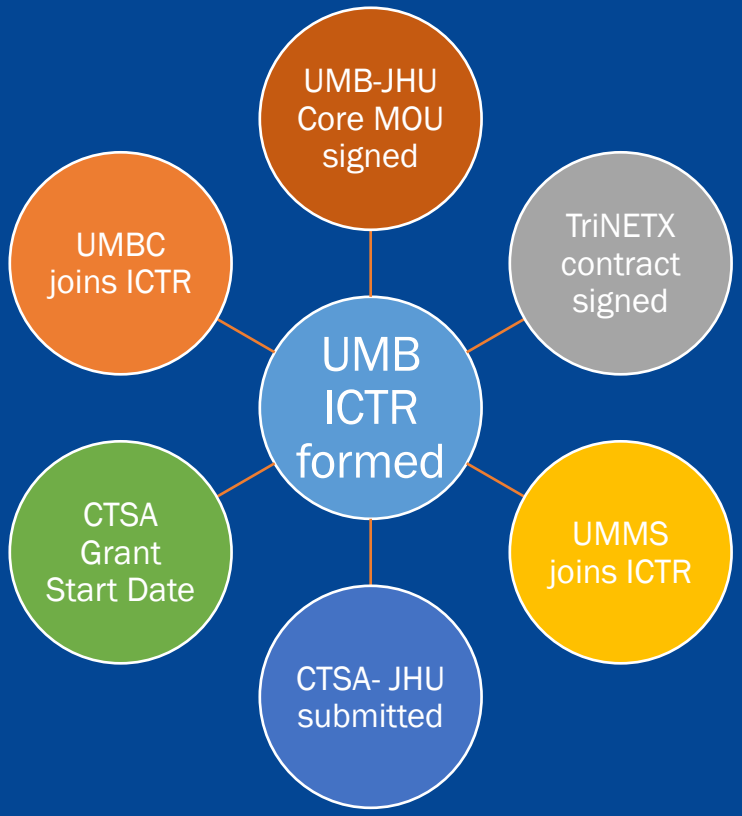
Network Capacity

- Liaison to Trial Innovation Centers (TICs)
- Liaison to Recruitment Innovation Centers (RICs)

Hub Research Capacity

- Integrating Special Populations
- Participant and Clinical Interactions

ICTR Ecosystem



In Progress:

- UMMS-UMB Clinical Research Network
- UMCP

Dec. 3, 2017 → April 18, 2018 → May 25, 2018 → May 31, 2019 → July 1, 2019 → Sept. 9, 2020 → Sept. 21, 2020

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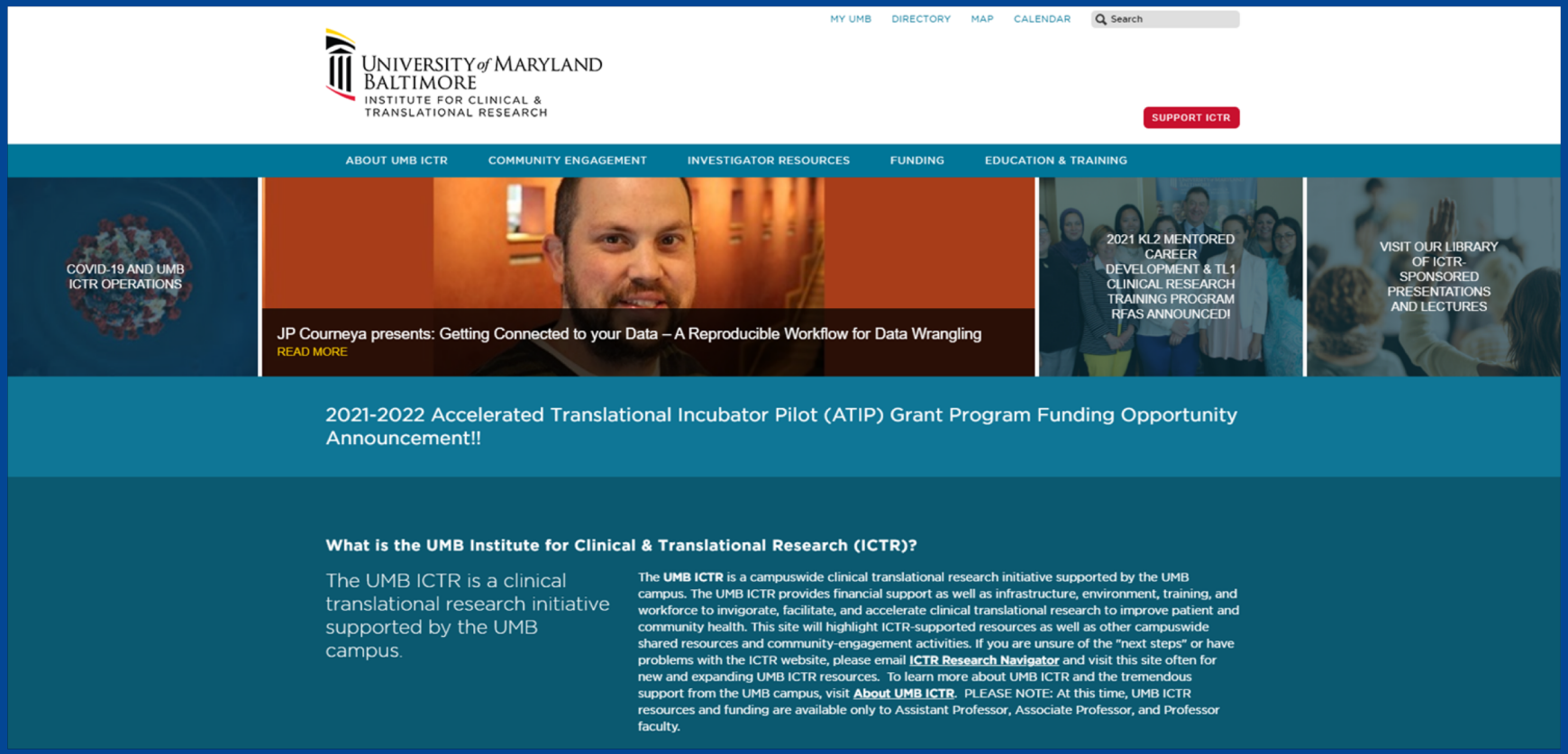
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