

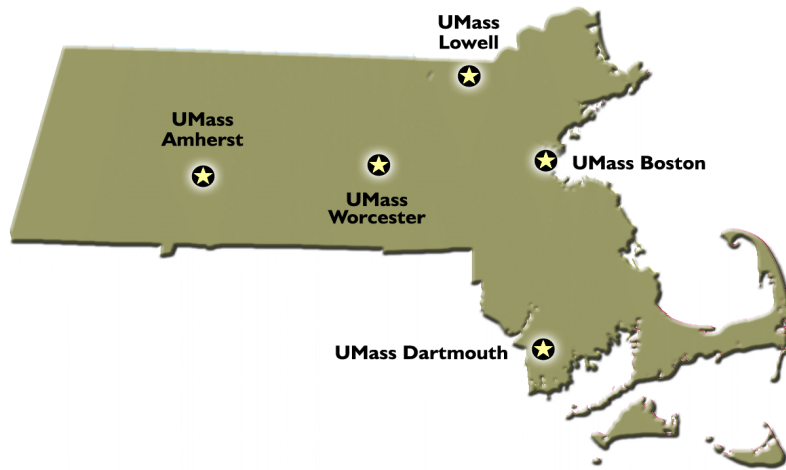
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Overview of Translational Biomedical Research and the UMass Center for Clinical & Translational Science

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Overview of Translational Biomedical Research and the UMass Center for Clinical & Translational Science



John L. Sullivan, MD
Professor of Pediatrics and Molecular Medicine
Director, UMass Center for Clinical Translational Science
Vice Provost for Research

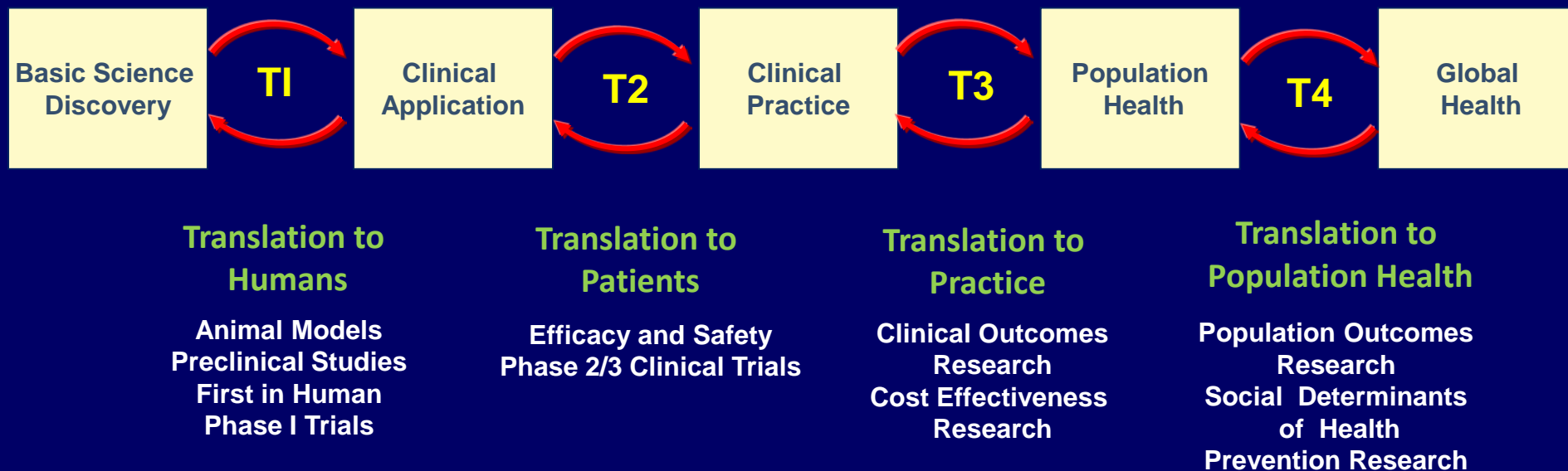
The UMass CTSA Grant

- **On July 14, 2010, the University received a 5-year, \$20 million Clinical and Translational Science Award from the NIH**
 - **Joins an elite consortium of 60 nationally prominent research institutions**
 - **Terry Flotte, MD, Dean of the School of Medicine, and John Sullivan, MD, Vice Provost for Research at the Medical School serve as Co-Principal Investigators on the grant**
 - **Partners include the UMass campuses, UMass Memorial Health Care, Commonwealth Medicine, MassBiologics, Abbott Bioresearch Center, Charles River Labs, New England Regional Translational Network and WPI**

UMCCTS – Primary Goals

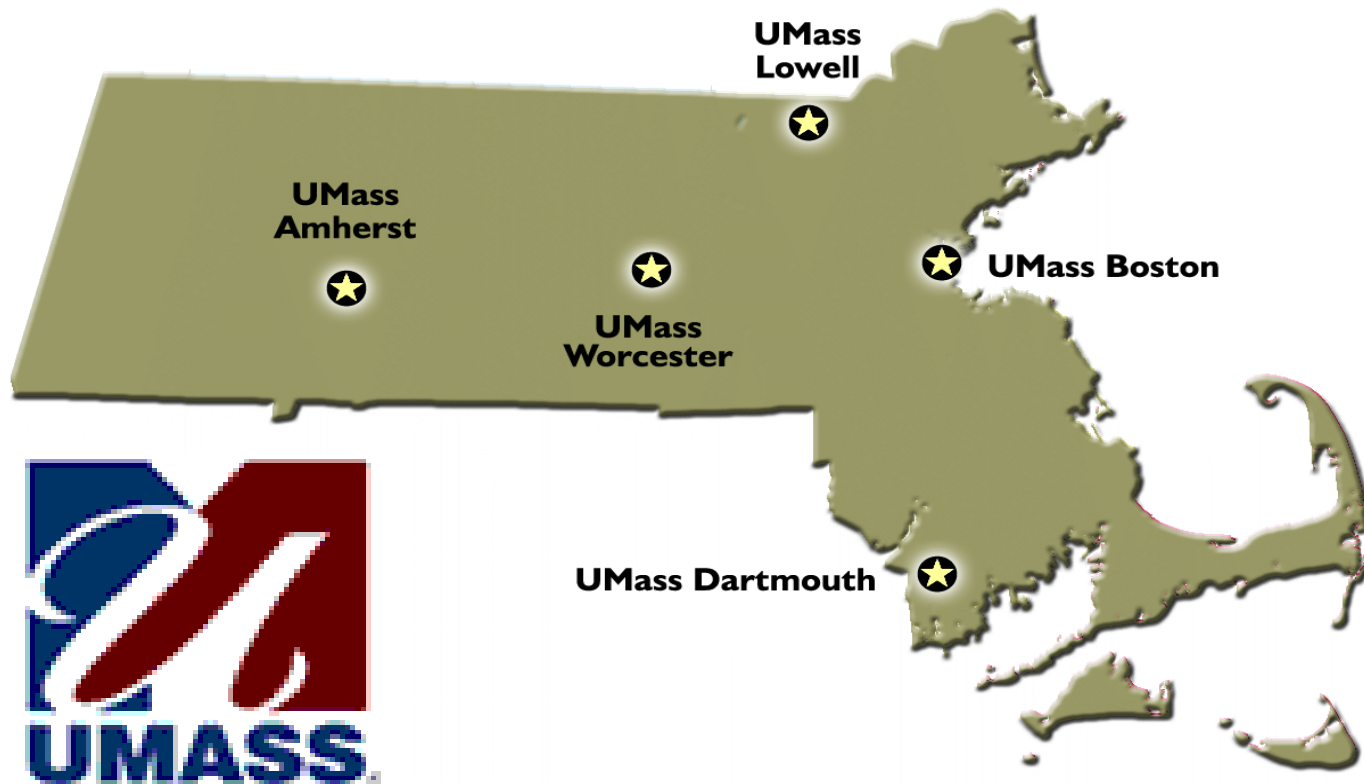
- **Accelerate** early phase clinical trials by recruiting and supporting clinical research leaders, establishing innovative research support facilities and developing new therapeutics based on UMass discoveries
- **Integrate** unique networks of clinical research and health care delivery in central New England and throughout Massachusetts to expand later phase clinical trials
- **Build** collaboration among the three schools of UMMS and across the five UMass campuses in developing programs, curricula and faculty support systems that foster and promote careers in clinical and translational research

Translational Research Model

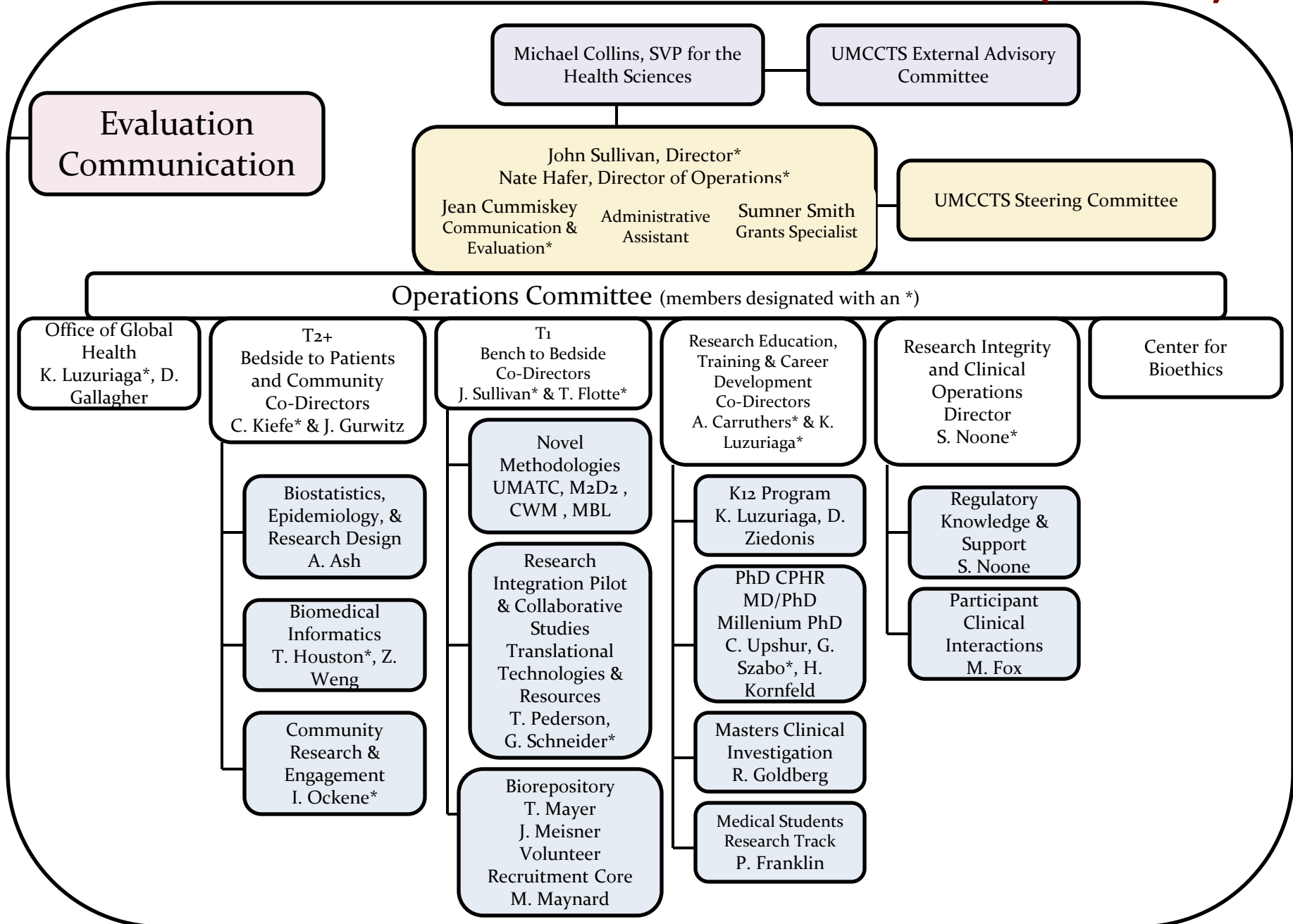




The UMCCTS includes faculty, staff, and students at all 5 UMass campuses



UMass Center for Clinical and Translational Science (UMCCTS)



Michael Collins, SVP for the Health Sciences

UMCCTS External Advisory Committee

Evaluation Communication

John Sullivan, Director*
Nate Hafer, Director of Operations*

Jean Cummiskey
Communication & Evaluation*
Administrative Assistant
Sumner Smith
Grants Specialist

UMCCTS Steering Committee

Operations Committee (members designated with an *)

Office of Global Health
K. Luzuriaga*, D. Gallagher

T2+
Bedside to Patients and Community
Co-Directors
C. Kiefe* & J. Gurwitz

Biostatistics, Epidemiology, & Research Design
A. Ash

Biomedical Informatics
T. Houston*, Z. Weng

Community Research & Engagement
I. Ockene*

T1
Bench to Bedside
Co-Directors
J. Sullivan* & T. Flotte*

Novel Methodologies
UMATC, M2D2, CWM, MBL

Research Integration Pilot & Collaborative Studies
Translational Technologies & Resources
T. Pederson, G. Schneider*

Biorepository
T. Mayer
J. Meisner
Volunteer Recruitment Core
M. Maynard

Research Education, Training & Career Development
Co-Directors
A. Carruthers* & K. Luzuriaga*

K12 Program
K. Luzuriaga, D. Ziedonis

PhD CPHR MD/PhD Millennium PhD
C. Upshur, G. Szabo*, H. Kornfeld

Masters Clinical Investigation
R. Goldberg

Medical Students Research Track
P. Franklin

Research Integrity and Clinical Operations
Director
S. Noone*

Regulatory Knowledge & Support
S. Noone

Participant Clinical Interactions
M. Fox

Center for Bioethics



UMCCTS Membership

- **Membership is open to all members of the UMass research community, provided that they are engaged in some aspect of clinical or translational research:**
 - **Over 300 colleagues from the campuses have already become members**
- **Benefits of membership include:**
 - **Access to core facilities and services operated by, or affiliated with, the UMCCTS**
 - **In the case of cores operating on a fee-for-service basis on the Worcester campus, members will receive the on-campus faculty rate**
 - **Access to the Medical School Library, including on-line subscriptions**
 - **Participation in education, training and scientific programs sponsored by the UMCCTS**
 - **Opportunity to apply for pilot grant funding through the UMCCTS**

Nate Hafer's Job:

**To help you identify resources available
through the CCTS and understand how these
resources can benefit your research**

nathaniel.hafer@umassmed.edu

508-856-2511

<http://www.umassmed.edu/cts/index.aspx>

Pilot Project Program

Specific Aims:

- 1. Stimulate the development of new clinical and translational inter- and multi-disciplinary teams**
- 2. Provide novel support mechanisms for junior investigators**
- 3. Increase the emphasis on pilot funding for community-engaged research**
- 4. Develop new methodologies to leverage institutional strengths and new initiatives**
- 5. Pursue high-risk, high reward studies**
- 6. Support projects utilizing the unique core facilities at the medical school and throughout the University**
- 7. Encourage collaboration across the five UMass campuses**

UMCCTS Pilot Grant Programs 2009-2011

- 1. Life Sciences Moment Fund \$1.5M**
- 2. Pilot Project Program \$2.1 M**
- 3. WPI/UMMS Collaborative Pilot Project Program \$600K**

2010 Life Sciences Moment Fund Recipients (3rd Funding Cycle)

UMMS Collaborator(s)/Dept	UMass Collaborator/Dept	Project Title
<p>Patricia Franklin, MD, MPH, MBA Joy McCann Professor</p>	<p>Patty S. Freedson, PhD Professor and Chair, Kinesiology Amherst campus</p>	<p>Technology to assess physical activity and sedentary behavior in aging adults with osteoarthritis</p>
<p>Alonzo Ross, PhD Professor, Biochemistry and Molecular Pharmacology Phillip Zamore, PhD Professor, Biochemistry and Molecular Pharmacology</p>	<p>Lisa Minter, PhD Assistant Professor, Department of Veterinary and Animal Sciences Amherst campus</p>	<p>Targeting microRNAs to Enhance a Novel Therapy for Glioblastomas</p>
<p>Gary Ostroff, PhD Professor of Molecular Medicine Hardy Kornfeld, MD Professor of Medicine</p>	<p>Gregory N. Tew, PhD Associate Professor, Polymer Science & Engineering Amherst campus</p>	<p>Targeted Delivery of Novel Antimicrobial Peptide Mimics to TB</p>
<p>Celia Schiffer, PhD Professor, Biochemistry & Molecular Pharmacology</p>	<p>Margaret Riley, PhD Professor of Biology Amherst campus</p>	<p>Testing novel antimicrobials to treat chronic Pseudomonas aeruginosa infections in CF lung</p>
<p>Andrew Karellas, PhD Professor of Radiology</p>	<p>David Medich, PhD Director, Radiation Safety Peter Gaines, PhD Assistant Professor, Molecular and Developmental Biology /Lowell campus</p>	<p>Feasibility of Contrast Enhanced Neutron Imaging for the Early and Accurate Detection of Disease</p>

Education, Training, and Career Development

Our goal is to expand the critical mass of expert scientists undertaking clinical and translational research by training healthcare professionals, basic scientists, junior faculty, postdoctoral fellows, graduate students, nursing students, medical students and research associates in the principles and practices of clinical and translational research.

UMCCTS – Faculty Development - KL2 Scholar

Recipient	Mentors
Olga Hardy, MD Department of Pediatrics	Drs. Czech and Lee
Wendy Marsh, MD Department of Psychiatry	Drs. Nicholson and Rothschild
Jeff Bailey, MD, PhD Department of Medicine, Program in Bioinformatics and Integrative Biology	Drs. Finberg and Weng
Sarah Cutrona, MD, MPH Department of Medicine	Drs. Gurwitz and Mazor
Heena Santry, MD Department of Surgery	Drs. Kiefe and Messina

UMCCTS Core Infrastructure

- 1. Quantitative Health Sciences Department – Quantitative Methods Core
Biostatistics/Epidemiology/Study Design**
- 2. Biomedical Informatics**
- 3. Conquering Diseases Clinical Research Center**
- 4. Conquering Diseases Biorepository and Research Volunteer
Recruitment Core**
- 5. Deep Sequencing Core**
- 6. Proteomics Core**

Massachusetts Integrated Clinical Academic Research Database (MICARD)

- Serves as an online catalogue for the Conquering Diseases Biorepository
- Offers a de-identified view of clinical phenotypes of UMMHC patients and their consented bio-samples
- These data will be most useful for investigators interested in:
 - Generating new research hypotheses
 - Preparing grant applications that would benefit from pre-identification and/or characterization of a potential research cohort
 - Identifying potential cohorts for clinical trials
 - Identifying consented biosamples from the UMMS Conquering Diseases Biorepository
- MICARD warehouse contains data on more than 2 million patients

Conquering Diseases Biorepository Core

- **A new resource for banking blood samples for biomedical research**
 - **Will store plasma, DNA and RNA**
 - **RNA storage a differentiating aspect of the Biorepository and reflects the world-class strength of the medical school's RNA research community**
 - **Provide researchers with a pool of de-identified samples to work with**
 - **Information about patients' age, gender, diagnoses and medications, allowing for comparison of one sample to the next**



- **Biorepository samples are collected from members of the community who support biomedical research by giving their consent, rather than being obtained as discarded blood samples**
 - **This approach allows nearly all specimens to reach thermal preservation within 1 hour of collection**

Conquering Diseases Clinical Research Center



- Offers investigators the space, staff and resources to conduct their clinical studies and trials efficiently
- Welcoming area for study subjects, the CRC comprises 5,000 sq ft, including 6 exam rooms, 3 infusion bays, a small laboratory for packaging & shipping specimens, conference room space for monitor and study initiation visits, and touch-down space for visiting staff and investigators
- Staff includes a research nurse manager, four experienced research nurses, two investigational pharmacists, a regulatory support coordinator and a receptionist/administrative assistant

Research Integrity and Clinical Operations

- **Create central hub for Clinical Research Resources and Regulatory Knowledge & Support**
- **Ensure *clinical researcher* best practice ('GCP') by promoting enhanced knowledge and skills**
- **Enhance *institutional* knowledge and support: *ensuring best practice is shared responsibility***

Research Integrity and Clinical Operations

- Continuing Education & Training
- *New Certificate in Clinical Research Management:*
 - CCTS and Graduate School of Nursing; CEU-based
 - Deepen regulatory knowledge for FDA-regulated trials and translational research; strengthen support for investigator-initiated research
 - Started March 2011
 - Cost \$350 – includes contact hours and book
 - Co-directors: Sheila Noone & Carol Bova
 - http://www.umassmed.edu/news/research/2011/human_trials.aspx

Center for Bioethics

- **Education, research, and consultation in bioethics are critical as the clinical research enterprise expands at UMMS/UMMHC**
- **2 outstanding candidates have been accepted to the Fellowship Program in Medical Ethics at Harvard Medical School**
- **The successful candidate(s) will play a key role in the development of a Center for Bioethics as part of the UMCCTS**



Pfizer Centers for Therapeutic Innovation - CTI

National Center for Advancing Translational Sciences October 2011

- **Highest Priority of NIH Director, Dr. Francis Collins**
- **Focused on Rapidly Advancing Opportunities to Prevent and Treat Disease**
- **Will Include National CTSA Network and Partnerships with FDA, Pharma and Biotech**
- **Success Measured by Catalyzing Collaborations Between *Basic Scientists and Physician Investigators***

National Center for Advancing Translational Sciences

October 2011

- **Clinical and Translational Science Awards**
- **Therapeutics for Rare and Neglected Diseases**
- **Cures Acceleration Network (\$100 Million)**
- **Rapid Access to Intervention Development**
- **Molecular Libraries Program**



Open Discussion and Questions