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

John L. Sullivan
University of Massachusetts Medical School

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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

Basic Science Discovery

Translation to Humans
- Animal Models
- Preclinical Studies
- First in Human Phase I Trials

Clinical Application

Translation to Patients
- Efficacy and Safety
- Phase 2/3 Clinical Trials

Clinical Practice

Translation to Practice
- Clinical Outcomes Research
- Cost Effectiveness Research

Population Health

Translation to Population Health
- Population Outcomes Research
- Social Determinants of Health Prevention Research

Global Health
The UMCCTS includes faculty, staff, and students at all 5 UMass campuses.
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
<table>
<thead>
<tr>
<th>UMMS Collaborator(s)/Dept</th>
<th>UMass Collaborator/Dept</th>
<th>Project Title</th>
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<tbody>
<tr>
<td><strong>Patricia Franklin, MD, MPH, MBA</strong>&lt;br&gt; Joy McCann Professor</td>
<td><strong>Patty S. Freedson, PhD</strong>&lt;br&gt; Professor and Chair, Kinesiology&lt;br&gt; Amherst campus</td>
<td>Technology to assess physical activity and sedentary behavior in aging adults with osteoarthritis</td>
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<td><strong>Alonzo Ross, PhD</strong>&lt;br&gt; Professor, Biochemistry and Molecular Pharmacology</td>
<td><strong>Lisa Minter, PhD</strong>&lt;br&gt; Assistant Professor, Department of Veterinary and Animal Sciences&lt;br&gt; Amherst campus</td>
<td>Targeting microRNAs to Enhance a Novel Therapy for Glioblastomas</td>
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<tr>
<td><strong>Phillip Zamore, PhD</strong>&lt;br&gt; Professor, Biochemistry and Molecular Pharmacology</td>
<td><strong>Gregory N. Tew, PhD</strong>&lt;br&gt; Associate Professor, Polymer Science &amp; Engineering&lt;br&gt; Amherst campus</td>
<td>Targeted Delivery of Novel Antimicrobial Peptide Mimics to TB</td>
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<td><strong>Gary Ostroff, PhD</strong>&lt;br&gt; Professor of Molecular Medicine</td>
<td><strong>Margaret Riley, PhD</strong>&lt;br&gt; Professor of Biology&lt;br&gt; Amherst campus</td>
<td>Testing novel antimicrobials to treat chronic Pseudomonas aeruginosa infections in CF lung</td>
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<tr>
<td><strong>Hardy Kornfeld, MD</strong>&lt;br&gt; Professor of Medicine</td>
<td><strong>David Medich, PhD</strong>&lt;br&gt; Director, Radiation Safety&lt;br&gt; Peter Gaines, PhD&lt;br&gt; Assistant Professor, Molecular and Developmental Biology /Lowell campus</td>
<td>Feasibility of Contrast Enhanced Neutron Imaging for the Early and Accurate Detection of Disease</td>
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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.
<table>
<thead>
<tr>
<th>Recipient</th>
<th>Mentors</th>
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<tbody>
<tr>
<td>Olga Hardy, MD</td>
<td>Drs. Czech and Lee</td>
</tr>
<tr>
<td>Department of Pediatrics</td>
<td></td>
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<tr>
<td>Wendy Marsh, MD</td>
<td>Drs. Nicholson and Rothschild</td>
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<tr>
<td>Department of Psychiatry</td>
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<tr>
<td>Jeff Bailey, MD, PhD</td>
<td>Drs. Finberg and Weng</td>
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<tr>
<td>Department of Medicine, Program in Bioinformatics and Integrative Biology</td>
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<tr>
<td>Sarah Cutrona, MD, MPH</td>
<td>Drs. Gurwitz and Mazor</td>
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<tr>
<td>Department of Medicine</td>
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<tr>
<td>Heena Santry, MD</td>
<td>Drs. Kiefe and Messina</td>
</tr>
<tr>
<td>Department of Surgery</td>
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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
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