Navigating the UCLA CTSI

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Research Facilitator
Office of Investigator Services

www.ctsi.ucla.edu
NCATS Clinical and Translational Science Award

UCLA CTSI is part of a national consortium of 60 medical research institutions

- **Accelerate** the process of translating laboratory discoveries into treatments for patients
- **Engage** communities in clinical research efforts
- **Train** a new generation of clinical and translational researchers

*Accelerating Discoveries Towards Better Health*
Purpose of the National CTSA Program

Providing an infrastructure for clinical and translational research

<table>
<thead>
<tr>
<th>OLD</th>
<th>NEW</th>
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<tbody>
<tr>
<td>Inpatient GCRC</td>
<td>Outpatient &amp; community based research</td>
</tr>
<tr>
<td>Individual investigators</td>
<td>Transdisciplinary team science</td>
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<tr>
<td>Traditional training</td>
<td>Training in clinical and translational team science</td>
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<tr>
<td>Individual academic medical centers</td>
<td>Regional and national consortia linked for collaboration</td>
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</table>
UCLA Clinical and Translational Science Institute

- Public research university with leading medical, dental, public health, nursing, engineering, business and life sciences
- Cedars-Sinai Medical Center is the largest nonprofit hospital in the western United States
- An academic institution serving the under-resourced Watts-Willowbrook communities of South Los Angeles
- Public teaching and research hospital; its catchment area of 3 million residents includes 550,000 below the poverty level
> 10 million people
- no ethnic majority
- 107 languages
- The county’s population is larger than that of 42 states
- 30% are under age 18 and 20% are below the federal poverty line
- 25% lack health insurance
- A 15-year life expectancy gap separates our healthiest and sickest populations

Adapted from SUSTAIN presentation, Vickrey, 2011

Mission: Create a borderless clinical and translational research institute that brings UCLA innovations and resources to bear on the greatest health needs in Los Angeles.
UCLA CTSI Program Areas

Consultation, support services and resources available:

### Biomedical Informatics Program
- Resources and infrastructure for acquisition, storage and analysis of data

### Biostatistics and Computational Biology
- Project design, biostatistics, clinical data management and computational biology

### Center for Translational Technologies
- Access to more than 100 biomedical cores across CTSI campuses

### Clinical and Community Research Resources
- Supports clinical research at the Clinical and Translational Research Centers

### Research Education, Training, and Career Development
- Conducts and coordinates clinical and translational science education

### Community Engagement and Research Program
- Links investigators and local communities, consultation program

### Evaluation Program
- Health services research, cost analysis, evaluations, surveys

### Pilot and Collaborative Translational and Clinical Studies Program
- Supports multidisciplinary pilot studies and the development of novel methodologies and technologies

### Regulatory Knowledge and Support, Industry Relations, and Research Ethics
- Regulatory compliance, IRB, data safety monitoring, post-approval oversight

### Committee on Maternal, Child and Adolescent Health
What is Translational Research?

UCLA CTSI translational investigation extends from molecules to society

Translating knowledge gained from laboratory science into clinical practice to improve health.

The aim of translational research is to produce new:

- Therapeutics
- Medical devices
- Tools for diagnosing disease
- Avenues for community engagement research
What is Translational Research?

**T1**
Translation to Humans

**T2**
Translation to Patients

**T3**
Translation to Practice

**T4**
Translation to Populations

- Improved global health
What is Translational Research?

**T1: Translation to Humans**

Basic discovery research findings are tested for clinical effect and feasibility

- preclinical and animal studies, first in human, proof of concept, phase 1 clinical trials

- Amira Brown “Effects of Varenicline on Alcohol and Nicotine Consumption and changes in Dopamine D2-like Receptor Availability in High-Alcohol Preferring Mice” *CDU CTSI KL2 Scholar*
- Steve Horvath and Enrique Lopez “Diagnostic and Prognostic Biomarkers for HIV-Associated Non-AIDS (HANA) Condition” *CTSI Team Science (UCLA and CSMC)*
- David Underhill “Interactions Between Commensal Fungi and the C-Type Lectin Receptor Dectin-1 Influence Colitis” *CTSI Voucher CSMC*
- Joshua J. Zaritsky “Hepcidin and the Anemia of Chronic Kidney Disease” *UCLA KL2 Scholar, IRB Reliance with LA BioMed*
What is Translational Research?

**T2: Translation to Patients**
Clinically test interventions in controlled environments to determine clinical application, results yield knowledge about safety and efficacy

- phase 2 and 3 clinical trials

- Ronald Victor “Tadalafil Alleviates Muscle Ischemia in Patients with Becker Muscular Dystrophy” *CTSI Biostats CSMC*
- Noah Craft “Treatment of Visceral Leishmaniasis with Topically Applied TLR Agonists” *CTSI voucher LA BioMed*
- Antoni Ribas “Overcoming acquired resistance to B-Raf targeting in melanoma using phospho-proteomics and microfluidics” *CTSI Team Science UCLA*
- Satiro De Oliveira “Anti-leukemic Immunotherapy Using Modification of Hematopoietic Stem Cells” *CTSI Voucher UCLA*
T3: Translation to Practice

Explore ways to implement recommendations from clinical studies to general practice

- phase 4 clinical trials, health services research, clinical outcomes research

- Kara Chew “Clinical and Translational Science Institute Prospective Longitudinal Assessment of Coinfected Subjects with HIV/Hepatitis C for Endothelial Function Study” *CTSI CTRC pilot and BIP UCLA*
- Erin Hahn “Cancer Survivors and Survivorship Care” *CTSI TL1 Pre-doctoral fellow UCLA*
- Chrisandra Shufelt “Estrogen Deficiency and Cardiovascular Disease in Premenopausal Women” *CTSI KL2 scholar CSMC*
T4: Translation to Population Health

Examine factors and interventions that influence the health of a population.

- population outcomes research, social determinants of health

- Ronald Victor “Barber Intervention for Hypertension” Biostats and CTSI Team Science CSMC
- Barbara Vickrey “Stroke/cardiovascular disease in underserved minority populations” CTSI Team science UCLA
- Ozioma Nwosu “Fruit and Vegetable Intake and Mortality in U.S. Adults” CTSI TL1 Summer Fellowship CDU
- Josheph E. Gaugler (Univ Minn) and Joshua Chodosh (UCLA) “Alzheimer's Disease Coordinated Care for Hispanic and Latino Seniors” CERP Team Science Pilot UCLA and UMinn
UCLA CTSI and Translational Research

CTSI program areas offer support and resources throughout T1 to T4 translational research.

Core Facilities
Research Ethics
Education and Training
Community Engagement

Basic Discovery Research
Clinical Insights
Implications for practice
Implications for community
Improved global health

Collaborations
Regulatory
Biostatistics
Health Services Research

Funding Opportunities

CTSI program areas offer support and resources throughout T1 to T4 translational research.
# UCLA CTSI Funding Mechanisms

<table>
<thead>
<tr>
<th>Opportunity Funds</th>
<th>Grant Amount</th>
<th>Duration of Award (Years)</th>
<th>Award Cycle</th>
<th>Application Due Date</th>
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<tbody>
<tr>
<td><strong>Vouchers</strong>: for core services at CTSI institutions</td>
<td>Up to $10,000</td>
<td>1</td>
<td>Biannual</td>
<td>Fall 2013</td>
</tr>
<tr>
<td><strong>Team Science Awards</strong>: multidisciplinary, cross-institutional, translational science leading to a proposal under such team-science mechanisms as P01, U54, and center grants</td>
<td>Up to $200,000</td>
<td>1-2 years</td>
<td>Annual</td>
<td>Rolling</td>
</tr>
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<td><strong>Catalyst Awards</strong>: to support seminar series, team-building activities and other activities to encourage translational team science</td>
<td>$1,000 to $5,000</td>
<td>Up to 1 year</td>
<td>Quarterly</td>
<td>Application due August 1, 2013</td>
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Please visit [www.ctsi.ucla.edu](http://www.ctsi.ucla.edu) for more information and a list of open opportunities.
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<td><strong>Scholar Awards:</strong> for junior faculty in any series within their first three years of appointment to support mentored training in translational research in all areas of investigation</td>
<td>Up to $30,000</td>
<td>Up to 1 year</td>
<td>Annual</td>
<td>Fall 2013</td>
</tr>
<tr>
<td><strong>TL1 Translational Science Fellowship:</strong> PhD candidates in the Department of Health Services in the UCLA School of Public Health receive mentored training to ensure the translational nature of their dissertation projects</td>
<td>Annual stipend plus funding for health insurance, tuition/fees, and training-related travel</td>
<td>Renewable for up to 4 years</td>
<td>Annual</td>
<td>Fall 2013</td>
</tr>
<tr>
<td><strong>TL1 Summer Program for Professional Students:</strong> provides professional students (medical, nursing and dental) early exposure to interdisciplinary, community-partnered translational or health services research</td>
<td>Summer stipend plus funding for training-related expenses</td>
<td>The summer between student’s first and second year (8 weeks)</td>
<td>June 1</td>
<td>Early 2014</td>
</tr>
<tr>
<td><strong>KL2 Awards:</strong> to pursue interdisciplinary, mentored research with training</td>
<td>Up to $125,000 in salary and research support</td>
<td>1 year at 75% effort (renewable for up to 3 years)</td>
<td>July 1</td>
<td>Early 2014</td>
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UCLA CTSI Training Program in Translational Sciences

Supports the development and enhancement of core courses and in-depth training necessary for mastery of the fundamental skills, methodologies, theories, and conceptualizations of translational clinical investigation

• Track 1 - Individual courses option
  - Clinical Research Development Seminars and modules, no tuition

• Track 2 - Certificate of Completion
  - Structured two year part-time program, no tuition
  - Application due May 15

• Track 3 - Master of Science in Clinical Research
  - Two year full time, tuition required
  - Application due May 15

• Pathway – Certificate in Clinical and Translational Research
  - For DGSOM Medical Students
Reliance Model among partner sites:

- One IRB may rely on another for review and continuing oversight of research requiring full committee or expedited review.
- Considerations:
  - Recipient of prime award
  - Primary Study Site
  - IRB expertise
- Local ancillary approvals still required (COI, IBC, Radiation Safety)

Reviewing IRB:
- Review and continuing oversight of entire project at all sites, including AEs, protocol violations, unanticipated problems and complaints.

Relying IRB:
- Right to refuse to be the relying IRB. Provides local research oversight findings to reviewing IRB for final determination and reporting to regulatory agencies.
Support and supervise clinical research with access to resources across partner campuses:

- Outpatient services
- Inpatient services (UCLA, LA Biomed)
- Experienced Research Staff: Nurses, nutritionists, laboratory personnel
- Standardized Research Procedures
- Mobile (off-site) Services
- Metabolic and Nutrition Services
- Laboratory Services

For site specific information, please visit: [www.ctsi.ucla.edu/ctrc](http://www.ctsi.ucla.edu/ctrc)
• **UC Research Exchange (UC-ReX)**
  – Cohort discovery and recruitment for clinical studies across the 5 UC medical campuses (UCLA, UCSF, UCD, UCI, UCSD)
• **Los Angeles Data Repository (LADR)**
  – Link data from CTSI partners and expand to more LA-area provider organizations
  – Pursue both cohort discovery/recruitment and comparative effectiveness data
The CERP Consultation Service bridges the gap between academic researchers and community partners:

- Training in community-based research and health services research
- Connections with investigators and community partners
- Advice on study design and implementation
- Dissemination of research results

For more information call the CERP Consultation Desk at 310-794-8719
Research Facilitation
Provides across-the-board assistance and access to CTSI resources:

- Research project development: basic science to clinical research
- Letters of Support
- Compliance with institutional policies and procedures
- IRB, regulatory and FDA requirements
- Good Clinical Practices
- Recruitment and retention
- Community-based research
- Research resource referrals
- Domain expert (>75) referrals: biostats, study design, data management, biomedical informatics, ethics
- Collaboration networking within CTSI and beyond
- Tours/visits to research facilities

Contact a Facilitator

Cedars-Sinai Medical Center
Jerlyn Tolentino, MA
(310) 423-2475

Charles Drew University of Medicine and Sciences
Maria Diaz-Romero
(323) 249-5707

Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center
Alla Victoroff, PA-C or Terry Doherty
(310) 222-2503

University of California, Los Angeles
Marisa Briones, PhD
(310) 825-0791
UCLA CTSI Drug Development Series

From the Bench to the Clinic: Therapeutic Drug Development

<table>
<thead>
<tr>
<th>Date</th>
<th>Topic</th>
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<tbody>
<tr>
<td>Mar 4</td>
<td>The Business of Therapeutics</td>
</tr>
<tr>
<td>Apr 1</td>
<td>Process Mapping</td>
</tr>
<tr>
<td>May 6</td>
<td>Targets and Biomarkers</td>
</tr>
<tr>
<td>Jun 3</td>
<td>Therapeutic Antibodies (Location: CHS 63-105)</td>
</tr>
<tr>
<td>Jul 1</td>
<td>Small Molecule Drug Development</td>
</tr>
<tr>
<td>Aug 5</td>
<td>Strategic Planning</td>
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</tbody>
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Mondays at 4pm

UCLA: NRB auditorium
Charles Drew Univ: Augustus Hawkins Room - 3071
LA BioMed/ Harbor: RB3, Room 213

UCLA CTSI Office of Investigator Services Seminar Series

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<tr>
<th>Date</th>
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<tbody>
<tr>
<td>Mar 25</td>
<td>Training and External Grant Opportunities for Young Investigators</td>
</tr>
<tr>
<td>Apr 29</td>
<td>Clinical Research Study Design</td>
</tr>
<tr>
<td>May 20</td>
<td>Clinical Research Registration Requirements</td>
</tr>
<tr>
<td>Jun 24</td>
<td>Community Engagement</td>
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Mondays 12:00 – 1:00pm

UCLA: CHS 63-105
CSMC: Pacific Theaters Building, 4th floor Medical Genetics small conference room
Charles Drew Univ: COBB Room 131
LA BioMed/ Harbor: RB3, 2nd floor (room 213)

*NEW* Investigators May Request CTSI Services Online

A user-friendly portal on the CTSI website allows investigators to request a variety of assistance, including biostatistical support, clinical research services, and matchmaking to foster new community or inter-institutional collaborations. A UCLA log-in ID is required.

For more information: www.ctsi.ucla.edu (310) 794-CTSI or ois@ctsi.ucla.edu