Clinical and Translational Research Institute
What is Translational Medicine?

• Divided into three general categories:
  – T1—Understanding disease pathogenesis/etiology and developing new methods of treatment, diagnosis, and prevention
  – T2—Translation of clinical research results into clinical practice
  – T3—Comparative effectiveness of new treatments
Clinical and Translational Research Institute

• Mission: To translate innovative science into improved health
• Organized Research Unit (ORU) at UCSD
• Funding sources include:
  – Institutional funds
  – Clinical and Translational Science Award
  – Recharges for CTRI services
  – Grants and service agreements
  – Total funding to date: $23.4 M
Clinical and Translational Research Institute

- Affiliated institutions—LIAI, Salk, Sanford-Burnham, Ventor, SDSU, Palomar-Pomerado health, Rady Children’s hospital
- Rady School of Management—MBA program, new Project Management curriculum
- Moores Cancer Center
- School of Engineering—translational partner, affiliated with Von Liebig Center
- 600 members
  - About 30% of UCSD Health Sciences Faculty
  - Members at affiliated institutions
General organization of the CTRI

Six divisions

- Center for Clinical Research
- Biomedical Informatics
- Translational Research Technology
- Translational Research Alliance
- Education and Training
- Community Alliance
Idea to Innovation: Advancing Healthcare through the CTRI

**Research Funding**
- Seed Grants
- Library Screening
- Pilot Project Grants
- Industry Funding/Express License/Business Plans
- "Omics" Consultation & Analysis
- Biostatistics
- Clinical Data Warehouse Mining
- Clinical Trial Software/Database Management
- Biomarker Consultation & Assays
- Biorepositories & Sample Annotation
- IND/DSMP/DSMB/IRB
- Inpatient/Outpatient/Phase I Facility
- Clinical Cores/Subject Recruitment/Imaging
- Ethics Consultation & Support
- Education/Training (KL2, TL1, K30, Master's degree)
- Symposia, Lecture series
- CME, Outreach

**Data Management & Analysis**
- Biomarker Discovery
- Clinical Research
- Community-based Research

**Services & Infrastructure**
- Community Funding/Express License/Business Plans
- Clinical Data Warehouse Mining
- Clinical Trial Software/Database Management
- Biostatistics
- "Omics" Consultation & Analysis
- Biorepositories & Sample Annotation
- IND/DSMP/DSMB/IRB
- Inpatient/Outpatient/Phase I Facility
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CTRI supplements and support

Peer Reviewed, Federal, Foundation and CTRI funded studies:
- CTRI provides up to 30% co-funding for services
- Eligible for co-funding of services up to $25k/year for 3 years
- Reviewed by service director(s)
  Feasibility and safety review (for clinical projects)

Industry Sponsored Projects:
- Investigator pays full cost of service
- Reviewed by service director
  Feasibility and safety review (for clinical projects)

K-awardees
Comparative foundation mentored awards:
- CTRI provides up to 60% co-funding for services
- Reviewed by service director(s)
  Feasibility and safety review (for clinical projects)

Pre-award statistical assistance:
- No charge for up to 4 hours of assistance
- Reviewed by service director
General organization of the CTRI
Center for Clinical Research Services

• Personnel
  – Clinical Coordinators and Nurses
  – Rady Children’s Hospital

• Other services (phlebotomy, skin biopsy, DEXA, exercise physiology)

• Biostatistics Core—no pre-award cost

• Design, Ethics, and Safety Review

• Space for research
  – Hillcrest (inpatient)
  – La Jolla (outpatient and overnight stays)
General organization of the CTRI
Biomedical Informatics

• BioComputational Center
  – Consultation and data analysis
    • Next Generation Sequencing
    • Epigenetics
    • Plans (proteomics, metabolomics)

• Medical Informatics
  – Clinical Data Warehouse for Research
  – Clinical Trial Management Software (Velos)
  – REDCap
  – CRIQuet
Biomedical Informatics—CRIQueT

- Searchable database in CDWR
- De-identified
- IRB approval not needed

Examples
- Parkinsons 1200 patients
- Alzheimers 1200 patients (750 females, 450 males)
- SLE 1000 patients (240 with C4 <12 mg/dl)
- CHF 4600 patients (300 with creat >2.0 mg/d in last 5 months)

- Identify patients with IRB approval
- In progress—Linking 5 UCs via UC ReX
Translational Research Technology

• Biosample repository—Sample collection, processing and tracking

• Biomarker Laboratory
  – CTRI-run facilities (Luminex, Mesoscale, Nanopro)

• Consortium of technologies
  – fMRI—CTRI matching funds for pilot projects
  – Mass Spec—Seed grant program
  – Tissue imaging core—Web based imaging purchased by CTRI
  – High throughput screening—Seed grant program
  – Genomics Core (Sanford Consortium)—Funding project scientist
Education

• KL2 program
  – Institutional K award

• Roadmap TL1
  – Equivalent to T32
  – Pharmacy and Medical Student research experience

• K30 CREST program
  – Individual modules
  – Master’s degree

• Symposia and other programs
  – Rady Health Sciences MBA
  – Project management course
Community Alliance

- Community Advisory Board
- Assistance with design of community-based projects
- Pilot project grants for community-based projects
- Research Match—Link researchers to participants

- Science Fair, Facebook, Twitter, Public forums
Translational Research Alliance

- Translational Alliance
  - Salk Institute
  - Sanford-Burnham
  - La Jolla Inst Allergy and Immunology
  - J Craig Ventor Institute
  - Institute of Engineering in Medicine

- Biological sample transfer, technology transfer
- Pilot project grants
- Industry collaborations (Pfizer, Roche, GSK, Takeda, Bayer, etc)
- Industry Advisory Council
Translational Research Alliance—Pilot projects

- Clinical Research
- Translational Research (including pre-clinical)
- Innovative Technology
- Seed grants
  - $2-8 K for CTRI services to support grant submission
  - 1-4 week turnaround
- Over $1 M in funding to date
Clinical and Translational Research Institute

- 7 funded KL2 junior faculty
  - Medicine, Biostatistics, Neuroscience, Surgery, Rad Oncology

- 63 TL1 Medical/Pharmacy students
  - 37 short term; 26 long term

- 96 K30/CREST enrollees

- 16 Master’s degrees in clinical research
Clinical and Translational Research Institute

- 82 active clinical research protocols
- 202 total protocols since 2010
- 66 letters of support for grants
- 39 publications
- 96 grants/clinical trials supported
- Supported $134 M in research grants in 2011
- 32 faculty using ResearchMatch
Clinical and Translational Research Institute

- 62 biostatistics consults
- 52 BioComputational Center consults
- Biomarker lab
  - 12,733 assays
  - 234 fluid and 84 tissue samples collected
  - 6 biorepositories managed
- Approx 100 skin biopsies for iPS
- 59 CRIQueT users
- REDCap
  - 84 projects
  - 199 users
Clinical and Translational Research Institute

- 33 pilot projects funded ($1 M)
  - 29 traditional pilot projects; 4 community projects
  - 7 papers, 7 abstracts published
  - 4 new grants (RO1, K23, foundation grants)
  - Pediatrics, Surgery, Medicine, Bioengineering, Psych, SPPS, Radiology
- 12 “seed” grants
- 4 Mass Spec mini grants
- High Throughput mini grants RFA
- 2 CTSA supplements ($1 M)
CTRI: Pilot project examples

- Innovative targeting of melanoma with allostERIC RAF inhibitors
- Neurocognitive effects of nicotine use in schizophrenia: parallel human and animal studies
- Pharmacogenetics in treatment refractory depression
- Premature infant nutrition post-discharge collaborative project
- Targeted nanosomai delivery of Imatinib to ameliorate renal damage from cis-platinum therapy for cervical cancer
- The role of type 1 interferon in allogeneic stem cell transplant
- Real-time wireless blood pressure monitoring for kidney disease
- Quantitative magnetic resonance assessment of secretions in cystic fibrosis airways
- Neurobiology of pain processing in children with gastrointestinal disorders
CTRI innovations

• Harmonization of IRBs among UC sites
• UC-wide Stem Cell Research Oversight Committee
• Master clinical trial agreements
• “Rapid review” IRB approvals
• Seven year IRB renewal
• “Express license” for start up companies
• Shared cores (mass spec, muscle imaging, fMRI)
• New biospecimen policy and governance for UCSD
• Implementation of UBMTA
• ResearchMatch
CTRI Website: ctri.ucsd.edu

Division of Clinical Research

The Division of Clinical Research is under the direction of Mark S. Wallace, MD. It contains services that facilitate performing all aspects of clinical research from “Concept to Completion” of the project. Included in this division are the following:

- Proposal Design Assistance
- Assistance with Regulatory issues and submissions
- Biostatistical Support including pre and post data collection
- Ethics consultation
- Consultation with community partners
- A cadre of trained clinical coordinators
- An inpatient and outpatient clinic dedicated to performing research studies
- An ombudsman, Michael Ziegler, MD who can assist junior investigators with navigating through the departments involved in conducting clinical research

Language Translation Services for Consent Forms and Other Documentation

CTRI members can contact Language Translation Services at info@languagetranslation.com or call (619) 510-4037. The current English to Spanish translation rate for UCSD investigators is $0.14 per word. LTI also provides translation services for many other languages, and the rates vary for each language. Translation
Year 3 Letter of Support

CTRI Letter of Support

CTRI Letter of Support for Funding Proposals

You must be a CTRI Member or Scholar or have membership pending to receive a CTRI Letter of Support.

The CTRI is unable to provide any CIRM grant support letters at this time. We are sorry for any inconvenience. If you need a CTRI support letter please contact Doris Dworschak at dddworschak@ucsd.edu.

If you would like the CTRI to provide a Letter of Support for your funding proposal, please complete the online form below. When all the information is complete a letter will be emailed to you within 5 business days. If any additional information is required someone from the CTRI Staff will get back to you. For questions regarding this, please contact Doris Dworschak at dddworschak@ucsd.edu or Angela Alexander at aalexander@ucsd.edu. Thank you.

Please complete the Letter of Support form.

CTRI Letter of Support Form

First Name

Last Name

Title (MD, PhD, Professor, etc)

E-Mail Address

Phone Number
$5 M for UC ReX funded by UCOP for systemwide CDWR
Planned funding for multi-center trials, coordinating UC cores, drug development
CTRI Space

[Map showing the location of the CTRI Space, with marked areas labeled as East Campus Office Building and East Campus Parking Lot.]
CTRI facility—East Campus
CTRI space—East Campus Office Building
Altman CTRI Building
CTRI Building—Clinical research floor
CTRI Building—Wet and Dry Lab Space
Future plans

• Expand current services and increase utilization
  – BioComp Center
  – Tissue Acquisition
  – Informatics tools, e.g., Velos

• Improved web interface

• Greater involvement of TRA partners

• Integrate new biomarker and imaging technologies

• Communication strategy to increase awareness

• Improved metrics and tracking