Welcome!

Science Café

Translating Research into Better Health
CTSI Leadership

Bruce Cronstein, MD
Director
Clinical and Translational Science Institute

Judith Hochman, MD
Co-Director
Clinical and Translational Science Institute
Opening Remarks

• Established in 2009 through a Clinical and Translational Science Award (CTSA) from the National Center for Advancing Translational Sciences (NCATS)
• Unites wide array of partners with diverse structures and missions
• Faculty are from the schools and colleges of NYU and clinical faculty at the associated hospitals
• Engaging faculty from NYU’s schools and colleges has broadened the scope of the research and resulted in innovative multidisciplinary approaches to solving health problems
• The CTSI has successfully catalyzed the development of new clinical and translational projects and promoted cutting edge studies by initiating the formation of collaborative teams
Mission Statement:
The CTSI promotes collaboration and cross-disciplinary translational research and training to support the efficient and safe application of scientific discoveries from bench to bedside to community.
CTSI Overview: Organization

Executive Vice President for Health
Robert Berne
New York University

Sr. VP & Vice Dean for Science, Chief Scientific Officer
Dafna Bar-Sagi
New York University School of Medicine

Partner Institutions

NYULMC: School of Medicine, Multisite Care Delivery System
New York University Schools & Colleges
New York City Health and Hospitals Corporation
Nathan Kline Institute for Psychiatric Research
Community Partners

CTSI Executive Leadership
UL1 MPI – Bruce Cronstein, MD
UL1 MPI – Judith Hochman, MD
Deborah Chavis-Keeling, MS

KL2 - MCD
PI – Michael Pillinger, MD

TL1 - NRSA
PI – Christine Kovner, PhD, RN

Advisory Boards
Internal Advisory Committee
External Advisory Committee
Community Advisory Board

Executive Committee
Executive Leadership & Partner Liaisons

Council
Executive Committee, Program, Unit & Core Directors

Review and Expertise
Scientific Review Committee
Recruitment/Retention Committee
Voucher Review Committee

NRO
REM
RIP
TSB

Evaluation & Continuous Improvement
Cross-cutting Working Groups

Translating Research into Better Health
CTSI Overview: Meet the Team

Deborah Chavis-Keeling
Lourdes Velasquez
Juan Suarez
Ryan Washington
Claudia Galeano
Catlin Rideout
Smiti Nadkarni
Rachel Thornton
Sandra Rodriguez
Keith Brown
Daniel Cobos
What Can the CTSI Do for You?

• We are here to facilitate innovative clinical and translational research at the School of Medicine and our partners at the Schools and Colleges of NYU, NYC Health and Hospitals, and Nathan Kline Institute

• We have developed a variety of tools and services designed to support research, training, education, and community engagement
What Can the CTSI Do for You?

Methods & Expertise
- Recruitment and Retention Unit
- Integrating Special Populations
- Community Engagement & Population Health Research
- Biostatistics & Study Design

Resources & Facilities
- Clinical Research Center
- Research Concierge & Regulatory Knowledge
- NYC Health + Hospitals
- Center for Biospecimen Research & Development
- Team Science

Training & Education
- KL2 & TL1 Training Programs
- Degrees and Certificates
- Mentor Development Program
- Seminars & Symposia

Funding & Development
- Pilot Projects
- Voucher Program
- Studio Program
- Science Interest Groups

Ancillary Programs
- Research Mission Programs
- Association of Clinical Coordination and Research Management
- DataCore & Informatics
- Library Services
- Human Research Regulatory Affairs & Research Regulatory Services

Translating Research into Better Health
CTSI Overview

Visit our website for more information:

ctsi.med.nyu.edu

And...don’t forget to cite us!

“Supported in part by the NYU CTSA grant UL1 TR001445 from the National Center for Advancing Translational Sciences, National Institutes of Health.”
Ancillary Programs

Human Research Regulatory Affairs

David Wallach, MPH, CIP
Director, Research Regulatory Services
OSR Human Research Regulatory Affairs
Quality Assurance (QA)/Quality Improvement (QI)

Enhanced QA/QI unit to proactively identify and help correct issues of non-compliance before any subject injury and before an external audit occurs.

Increased services to help prepare investigative teams with:
- Pre-audit services to help prepare for external audits
- Routine (not for-cause) audits to help address compliance issues before they become human subject protection issues
- Development of Corrective and Preventative Action (CAPA) plans that address human subject issues, with increased follow-up and guidance
Regulatory Support Services:
ClinicalTrials.gov Registration and Reporting

Registration and results submission handled by OSR since July 2015

Updates on regulation:
• Studies that meet the following criteria are required to be registered on ClinicalTrials.gov:
  o Involves a drug, device, or biologic subject to FDA regulation
  o Is a controlled clinical trial
  o Is not a Phase I study (drugs and biologics) or a feasibility study/study of a prototype (devices)
    - OR -
  o Is a clinical trial fully or partially funded by NIH*

• Results must be posted within 12 months of the Primary Completion Date, including statistical analysis* and study protocol*

*New with issuance of Final Rule and NIH supplement. Effective January 18, 2017
External/Central IRBs

Benefits of using central IRBs

• Reduce turnaround time
• NIH requirement of single IRB use for multi-site studies in 2017

Policy on use of external/central IRBs revisions (in process)

• Expands permissibility
• Establishes guidelines for acceptable external IRBs, and the situations they may be used

*Note: NCI CIRB and BRANY already in use*
Ancillary Programs

Research Mission Programs

Peter Hare, PhD
Associate Director, RMP
RESEARCH MISSION PROGRAMS (RMP)

• supports the preparation and submission of proposals for extramural funding

• is part of Research Enterprise and Strategy (RES) group in OSR

RES

Laura Ahlborn
Vice President for Research Enterprise

<table>
<thead>
<tr>
<th>RMP</th>
<th>Research Training</th>
<th>Planning &amp; Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metrics &amp; Dashboards</td>
<td>Engagement &amp; Reputation</td>
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</tr>
</tbody>
</table>

Jacqui Arciniega
Peter Hare
Sherri Burda
Eliana Castano
1. Find Funding

- Training/support to develop your own strategy
- Oversight of internal selection cycles for “limited” competitions and intramural funding

Extramural Funding

“Limited” Competitions

Intramural Funding

INTERNAL SELECTION

Announced though:
1) Broadcast emails
2) Intranet posts
3) Weekly OSR newsletter

NYU Langone Medical Center

OSR | Office of Science & Research
RMP SERVICES

2. Grant Editing

- No restrictions on type of proposal or career stage
- Get your near-final draft to RMP >14 working days before the deadline.
- SPA needs everything 7 working days before the sponsor’s deadline.

3. Project Management for Large Proposals

- Budget development
- Curation of letters of support, biosketches, subcontracts, and multiple-PI plans
- Services that complement departmental resources to enter data into Research Navigator and ASSIST
Ancillary Programs

DataCore and Informatics

Alex Bragat, PMP
Director, NYULMC DataCore
DataCore organization and services

NYULMC DataCore

Clinical Research Data Management
- Single Center Studies
- Multicenter Studies

Accessing Clinical Data for Research; Data Warehouse
- Clinical Data
- Claims Data
- Omics Data

Data Set Curation
- External Data Sets
- Internal Data Sets

Advanced Analytics
- NLP
- Machine Learning
- Predictive Modeling

DataCore services request form
## DataCore matrix of services

<table>
<thead>
<tr>
<th>Project Phase</th>
<th>Services</th>
<th>Clinical Data Management</th>
<th>Data Warehouse Extraction</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>DataCore</td>
<td>PI</td>
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<tr>
<td>Grant Development</td>
<td>Consultation/study planning</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td></td>
<td>Write data management sections</td>
<td>x</td>
<td>x</td>
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<tr>
<td></td>
<td>Budget development for DCC</td>
<td>x</td>
<td></td>
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<tr>
<td>Start-up</td>
<td>Database/eCRF build</td>
<td>x</td>
<td></td>
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<tr>
<td></td>
<td>Programming/testing</td>
<td>x</td>
<td>x</td>
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<tr>
<td></td>
<td>UAT</td>
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<td>x</td>
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<tr>
<td></td>
<td>Reports programming</td>
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<tr>
<td>Maintenance</td>
<td>User administration</td>
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<td></td>
<td>External data aggregation</td>
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<tr>
<td></td>
<td>Data migration</td>
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<td></td>
<td>Change controls</td>
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<tr>
<td></td>
<td>Data cleaning</td>
<td>x</td>
<td>x</td>
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<tr>
<td></td>
<td>Routine reports generation</td>
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<tr>
<td>Close-out</td>
<td>Database lock/unlock</td>
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<td></td>
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<tr>
<td></td>
<td>Full database extraction</td>
<td>x</td>
<td>x</td>
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<tr>
<td></td>
<td>Analyses datasets preparation</td>
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<td>x</td>
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<tr>
<td></td>
<td>Archiving/curcation</td>
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</tr>
<tr>
<td></td>
<td>Analytics</td>
<td>x</td>
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</tbody>
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Recently awarded grants with DataCore collaboration

**Long-term Suppressive Valacyclovir Treatment for Herpes Zoster Ophthalmicus**

**NYU Langone Awarded $7 Million by Government to Transform NYC Medical Practices**
Collaborative network will be led by NYU Langone, and joins federal government and other partners in supporting large-scale health care transformation.

New York, NY—A team from NYU Langone Medical Center will lead the Greater New York City Practice Transformation Network (NYC-PTN), one of 28 such networks across the country selected to participate in the Transforming Clinical Practice Initiative, announced recently by Health and Human Services Secretary Sylvia M. Burwell. The GNYC-PTN will receive up to $6.9 million to provide technical assistance support to help equip clinicians in the greater New York City region with tools, information, and network support needed to improve quality of care, increase patients’ access to information, and spend health care dollars more wisely.

**NYU Langone Medical Center Awarded $7.5 Million To Implement Support Services For Alzheimer’s Caregivers In New York City**
Earlier research from NYU Langone shows programs focused on well-being of caregivers provide benefit — to them and those for whom they care.

Dec 02, 2015, 12:10 ET from NYU Langone Medical Center

**CHIDS Awarded $4 Million by Government to Create a Patient Safety Laboratory**
Patient Safety Laboratory to be led by Center for Healthcare Innovation and Delivery Science Director Leora Horwitz and five Radiology and Population Health researchers.

New York, NY—Center for Healthcare Innovation and Delivery Science Director, Dr. Leora Horwitz, will lead a team of five researchers as they create the NYU Patient Imaging Quality and Safety Laboratory (PIQS Lab). The NYU PIQS Lab is one of 12 patient safety centers across the country funded in 2015 by the Agency for Healthcare Research and Quality (AHRQ).

Mar 25, 2016, 10:15 ET from NYU Langone Medical Center

**Department of Population Health Receives $15 million Federal Grant to Advance Heart Health**
Dr. Donna Shelley will lead HealthyHearts NYC, part of initiative under U.S. Department of Health and Human Services.

Wednesday, June 03 2015

The Department of Population Health at NYU Langone Medical Center, along with a cooperative team of health care and quality improvement experts, has been awarded a $15 million, three-year federal grant from the Agency for Healthcare Research and Quality (AHRQ) in the U.S. Department of Health and Human Services (HHS) to help primary care practices use the latest evidence to improve the heart health of millions of Americans. NYU Langone is one of only seven grant recipients nationwide to serve as part of the AHRQ initiative, EvidenceNOW — Advancing Heart Health in Primary Care. EvidenceNOW supports the broad HHS effort for Better Care, Smarter Spending, and Healthier People. EvidenceNOW also is aligned with HHS’s Million Hearts® national initiative to prevent heart attacks and strokes.

Dec 02, 2015, 12:10 ET from NYU Langone Medical Center
Ancillary Programs

Health Sciences Library

Alisa Surkis, PhD, MLS
Head of Data Services/Translational Science Librarian
Data Services

Classes, workshops, and consultations in the following areas:

• Research data management best practices
• Data Visualization best practices
• Complying with publisher and funder data requirements
• REDCap basics & advanced features
• Introduction to i2b2
• Poster design
• Data sharing

Data.DayToDay v2.0
Every Tuesday and Thursday at 10:00am from October 25 - November 17 2016
Data classes in the Sid & Ruth Lapidus Health Sciences Library
Click for more information
### 93 datasets
- 14 internal, 32 in pipeline, from 12 NYU researchers
- 28 NYULMC registry submissions
- 51 external datasets with local experts
Other Research Services

Classes, workshops, and consultations in the following areas:

• Literature searching
• Citation management
• Systematic, narrative, and scoping reviews

Access to large interactive visual display and 3D printing
Ancillary Programs

Association of Clinical Coordination and Research Management & Research Enterprise Training

Lois J. Mannon MS, RT CCRC
Director, Office of Research Education
The Research Enterprise Training unit is home to ACCRM, the health system advocate for improved research practice, professional development and education of our clinical study teams.
ENHANCE CLINICAL RESEARCH PROCESS

ESTABLISH A COMMUNITY OF COMMON PURPOSE

RECOGNIZE, ORGANIZE, AND DEVELOP OUR WORKFORCE
<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>2012</td>
<td>ACCRM Mission and Charter Exec Committee Selection Launch of ACCRM</td>
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<tr>
<td></td>
<td>ACCRMconnect Note to File Bulletin</td>
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<td>CRC Mentorship Program Certification Reimbursement</td>
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<td>2013</td>
<td>CRC In House Temp Program - Contact: Rachel Yuen, HR</td>
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<td></td>
<td>CRC Foundational Program - TransCelerate GCP Recognized - Offers 12 CEUs</td>
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<td>2014</td>
<td>Salary Structure Review</td>
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<td>Digital Handbook</td>
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<td>Advanced CRC Courses</td>
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<td>Clinical Skills Program at NYSIM Center</td>
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<tr>
<td>2015</td>
<td>Certification Differential Research Program Manager</td>
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<td>Leadership Recognition Award Program</td>
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<td>ACRP On-Demand Catalog</td>
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<td>2016</td>
<td>On-Boarding Brochure</td>
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<td>Recruitment Space, Feasibility, and Resources</td>
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<td></td>
<td>Clinical Skills Program Tuition Remission</td>
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<tr>
<td>2017</td>
<td>Goals To Be Determined</td>
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<td></td>
<td>November 8th 12-2pm</td>
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<td></td>
<td>Faculty Dining Room</td>
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Thank you!

See you at the ACCRM Biannual on November 8!