

# Welcome!



# 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

# CTSI Overview

**Deborah Chavis-Keeling, MS**

**Executive Director**

**Administration & Finance**

Clinical and Translational Science Institute

## **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

### KL2 - MCD

PI – Michael Pillinger, MD

### CTSI Executive Leadership

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

### TL1 - NRSA

PI – Christine Kovner, PhD, RN

### Advisory Boards

Internal Advisory Committee

External Advisory Committee

Community Advisory Board

### Review and Expertise

Scientific Review Committee

Recruitment/Retention Committee

Voucher Review Committee

### Executive Committee

Executive Leadership &  
Partner Liaisons

### Council

Executive Committee,  
Program, Unit & Core Directors

**NRO**

**REM**

**RIP**

**TSB**

Evaluation & Continuous Improvement

Cross-cutting Working Groups

# CTSI Overview: Meet the Team



Deborah Chavis-Keeling



Lourdes Velasquez



Juan Suarez



Ryan Washington



Claudia Galeano



Catlin Rideout



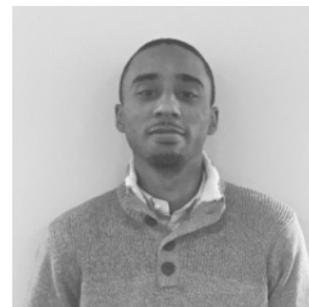
Smiti Nadkarni



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 & Symposiums

## 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

# CTSI Overview

**Visit our website for more information:**

[ctsi.med.nyu.edu](https://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

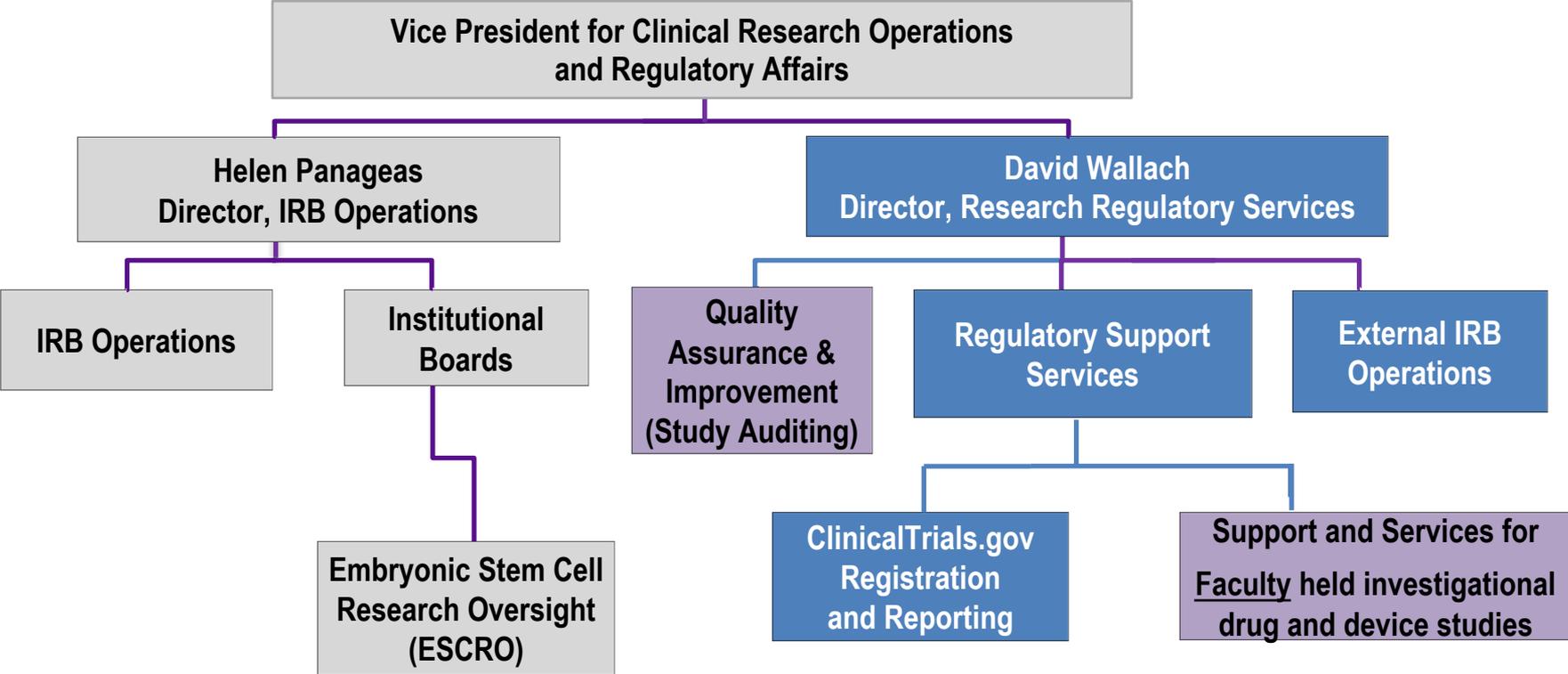
## Human Research Regulatory Affairs

**David Wallach, MPH, CIP**

Director, Research Regulatory Services

OSR Human Research Regulatory Affairs

# Human Research Regulatory Affairs Functions



- Previously existing, **unchanged** services
- Previously existing, **enhanced** services
- New** services



# 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:
  - Involves a drug, device, or biologic subject to FDA regulation
  - Is a controlled clinical trial
  - Is not a Phase I study (drugs and biologics) or a feasibility study/study of a prototype (devices)
- **OR** -
- 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)



Jacqui Arciniega



Peter Hare



Sherri Burda



Eliana Castano

- 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

RMP

Research Training

Planning & Analysis

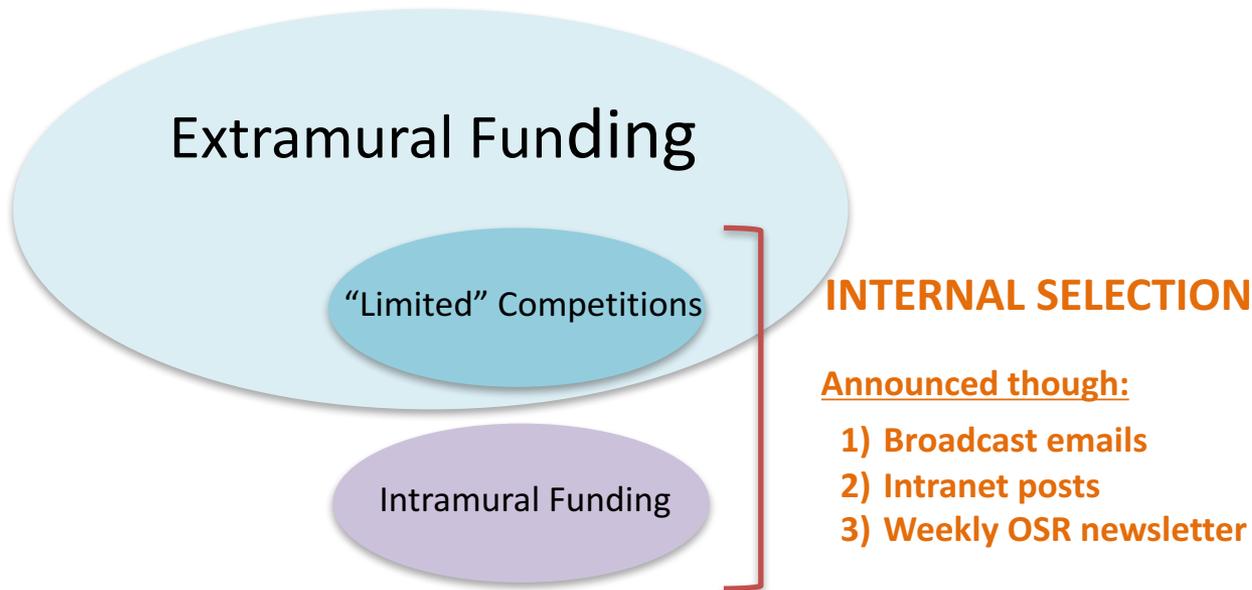
Metrics & Dashboards

Engagement & Reputation

# RMP SERVICES

## 1. Find Funding

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



# RMP SERVICES

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## 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

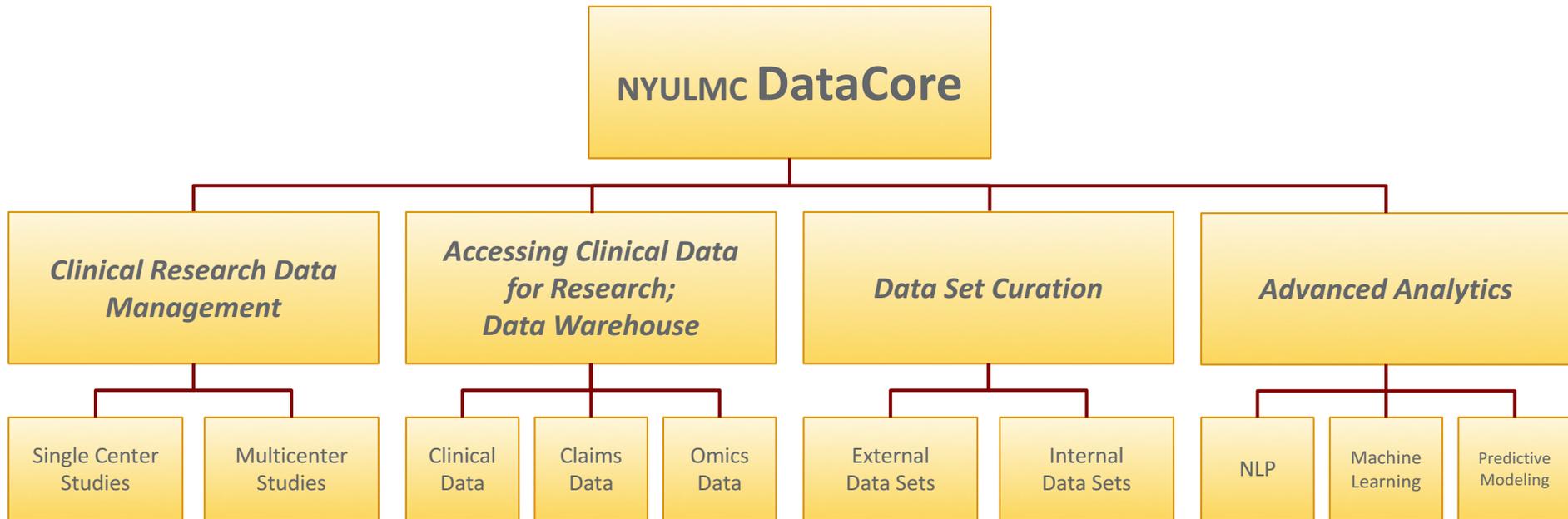
# Ancillary Programs

## DataCore and Informatics

Alex Bragat, PMP

Director, NYULMC DataCore

# DataCore organization and services



DataCore services request [form](#)

# DataCore matrix of services

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

# 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 (GNYS-PTN), one of 29 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 GNYS-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 Grant For New Nationwide Initiative To Study Heart Disease In Women

\$4 Million Grant from the American Heart Association to Support Research & Training at the Newly Created Sarah Ross Soter Center for Women's Cardiovascular Research

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

## 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).

## 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.

**EvidenceNOW**  
Advancing Heart Health in Primary Care



**HealthyHearts NYC**  
Primary care partnerships advancing heart health

# 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](#)**



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Filter by

Subject Domain

Delivery of Health Care	48
Population Characteristics	39
Quality of Health Care	37
Risk Factors	29
Health Status	20
Health Care Costs	14
Health Care Utilization	11
Chronic Disease	8
Cancer	4
Diabetes	2
Cardiovascular Diseases	1
Cognition Disorders	1
Tobacco Use	1

Geographic Coverage

New York (City)	40
National	33

AMA Physician Masterfile

<b>Description</b>	The Physician Masterfile includes education, training and professional certification information on virtually all Doctors of Medicine (MD) and Doctors of Osteopathic Medicine (DO) in the United States, Puerto Rico, Virgin Islands, and certain Pacific Islands. It includes current and historical data for more than 1.4 million physicians, residents, and medical students in the United States. This figure includes approximately 411,000 graduates of foreign medical schools who reside in the United States and who have met the educational and credentialing requirements necessary for recognition.
<b>Subject</b>	Delivery of Health Care Population Characteristics
<b>Geographic Coverage</b>	National
<b>Timeframe</b>	1906 - Present
<b>Access Rights</b>	Fee Required
<b>Local Expert</b>	Heather Gold

Action to Control Cardiovascular Risk in Diabetes Trial

<b>Alternate Title(s)</b>	ACCORD
<b>Description</b>	ACCORD was a large clinical trial examining methods of lowering the rate of cardiovascular disease in adults with type two diabetes. The study was composed of three clinical trials: an intensive lowering of blood sugar levels, intensive lowering of blood pressure, and treatment of multiple blood lipids with a combination of a fibrate and a statin. The study enrolled 10,251 adults beginning in 2001.
<b>Subject</b>	Chronic Disease
<b>Geographic Coverage</b>	International

93 datasets

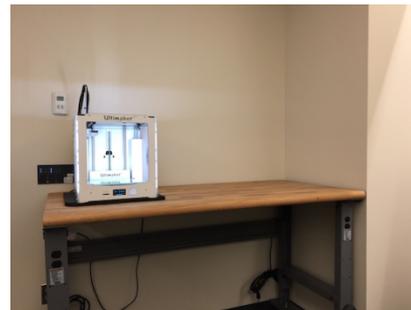
- 14 internal, 32 in pipeline, from 12 NYU researchers
- 28 NYULMC registry submissions
- 51 external datasets with local experts

## 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

Association of Clinical Coordination  
and Research Management  
**ACCRM Fall Biannual 2016**



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**



## ACCRM 2012

ACCRM Mission and Charter  
Exec Committee Selection  
Launch of ACCRM

ACCRMconnect  
*Note to File* Bulletin  
CRC Mentorship Program  
Certification Reimbursement

## ACCRM 2013

CRC In House Temp  
Program  
- Contact: Rachel Yuen, HR

CRC Foundational Program  
- TransCelerate GCP Recognized  
- Offers 12 CEUs

## ACCRM 2014

Salary Structure Review

Digital Handbook

Advanced CRC Courses

Clinical Skills Program  
at NYSIM Center

## ACCRM 2015

Certification Differential  
Research Program Manager  
Leadership Recognition  
Award Program  
ACRP On-Demand Catalog

## ACCRM 2016

On-Boarding Brochure  
Recruitment Space,  
Feasibility, and Resources  
Clinical Skills Program  
Tuition Remission

## ACCRM 2017

*Goals To Be  
Determined*  
November 8<sup>th</sup>  
12 -2pm  
Faculty Dining Room

**Thank you!**

**See you at the ACCRM Biannual  
on November 8!**