"Support for Your Clinical and Translational Research at CUMC"

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IRB Monthly Investigator Meeting
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ACCELERATING DISCOVERIES TOWARD BETTER HEALTH

Partially supported by an NIH Clinical and Translational Science Award (CTSA) through its Center for Advancing Translational Sciences, Grant No. UL1 TR00040.
Support for Your Clinical and Translational Research

- Pilot research awards
- Imaging awards
- Core Lab facilities
- CRC: in-patient and out-patient
- Community Engagement Center
- Health literacy service
- Consultation: Biostatistics, IRB, Bioethics, Database
What is the CTSA program?

A national consortium of medical research institutions, funded through NIH’s Clinical and Translational Science Awards (CTSAs), with the goals to:

- Improve the conduct of biomedical research across the country
- Reduce the time it takes for laboratory discoveries to become treatments for patients
- Engage communities in clinical research
- Train a new generation of clinical and translational researchers

There are 62 funded centers nation-wide. Funded since 2007 (Columbia was 1 of the 1st 12.)
Columbia’s CTSA = IRVING INSTITUTE

WHAT DO THE IRVING INSTITUTE RESOURCES PROVIDE?
What are the components of the Irving Institute?

Facilities:

• The 10th floor of 2 contiguous buildings (PH and Harkness)
• Adult inpatient and outpatient units
• Bionutrition unit with research kitchen
• Biomarkers Core lab (PH10)
• Pediatric outpatient unit (and virtual in-patient facility)
• Meeting and teaching space (PH10 stem)
• Administrative suite
Primary Core Resources – to serve CUMC Investigators

- TRANSFORM (educational programs)
- Pilot Studies Resource
- Biomedical Informatics Resource
- Design & Biostatistics Resource
- Regulatory Knowledge Support & Ethics Resource
- Clinical Research Center
- Community Engagement Resource
TRANSFORM Educational Resources

Provides long-term and short-term training and mentoring opportunities to a wide range of clinical and translational investigators, from pre-docs to junior faculty

Key Components:
- K12 Mentored Career Development Award (Assistant Professors),
- T32 MS in POR: Master of Science in Patient Oriented Research
- Short-Term training opportunities
  (e.g. Reach-for-the-R, Columbia Summer Research Institute - CSRI)

Plus: Masters in Patient-oriented research, Biostatistics, Bioethics
Pilot research funding

Provides seed funding for innovative, interdisciplinary research efforts – particularly those that bring together new investigative teams.

Key Components:

- **Pilot Awards:** With the CTO, the Irving Institute awards 8 one-year awards of $50,000 each (co-funded with dept.)
- **CaMPR Awards:** Provides 4 team-building grants ($15K) and 2 planning grants ($75K) for addressing an important problem at the cellular, individual, and community levels.
- Imaging awards
- OTHER

TIMELINES: Check the website:
www.irvinginstitute.columbia.edu
Design & Biostatistics Resource

Provides a wide range of design, statistical, and analytical support services to assist CUMC faculty with grant applications and publications.

Key Services:

- Several hours of a FREE consult (Available to CUMC INVESTIGATORS)
- Grant and manuscript preparation, including hypothesis writing, study design, analytic plans, and sample size justification
- Database consultation
Biomedical Informatics Resource

Roles: Providing information services to support clinical and translational research; conducting original informatics research on the nature of research processes and how information services can improve their efficiency

Key Components:

- **Web Portal**: Single entry point for all Irving Institute activities ([http://irvinginstitute.columbia.edu](http://irvinginstitute.columbia.edu)).

- **CUSP (CU Scientific Profiles)**: A unique search engine that incorporates information from HR, publication and grants databases that will allow investigators to identify new collaborators (in production).

- **Clinical Data Warehouse**: Permits users to query data on sets of patients, providers, departments, etc., for study planning.
Clinical Research Center

Provides research space and support to expedite and facilitate the collection of quality data in clinical and translational research

Key Components:

• Inpatient and outpatient space for adult and pediatric studies
• Long out-patient studies (up to 12 hours)
• Highly specialized research nursing services
• Clinical study coordinators
• Phlebotomy services
• Support for off-site studies in the ED, ICU’s
Community Engagement Resource

Organizes and guides investigators within and outside of CUMC who are involved in community based research, in order to enhance research efforts and more effectively communicate with our community partners.

Key Components:

- Consultation services
- Pilot awards for community researchers
- Columbia Community Partnership for Health, at 390 Ft. Washington Ave, featuring:
  - A bilingual health library
  - Health-related internet access for community residents
  - Interview and exam rooms for research
  - Conference rooms for health-related lectures and events
  - Pilot grants for training and research
Meeting area

Exam room for research
Regulatory Knowledge Support & Ethics Resource

Provides educational programming, training, and consultation on the entire range of regulatory requirements for the conduct of clinical and translational research

Training and consultation are available in the following domains:

• Research ethics (offering a master’s program in Bioethics, consultation)
• Regulatory/FDA requirements: IND/IDE Assistance Program
• Human subjects protection/IRB issues
• Clinical Trials Office/conduct of clinical trials
• Training targeted to research coordinators
The start of a new resource: Health Literacy for Research

Columbia University Human Research Protection Program

Protocol and Consent Document Templates, and Other Helpful Submission Forms

Protocol Templates
- Abbreviated IRB Submission for Multicenter Studies Sponsored by Industry or NIH Cooperative Groups
- Study Description Sample Text

Consent Document Templates
- Consent Form Builder Sample Language
- Genetics Research - Sample Text for Consent Form
- Incidental Finding Consent Template Language
- Minimal Risk Consent form template
- Minimal Risk Consent form template for studies involving audio/video recording
- Radiation Exposure Calculator and Risk Statements (Duke University)
- Standard Format for Social/Behavioral Science Consent Documents
- Consent Form Addenda regarding CUMC IRB Office move
  - English Addendum
  - Spanish Addendum

IRB Submission Forms:
- Analysis of Existing Data or Specimens
- Informed Consent Process
- Pathology Approval Form
Translational Technologies Resource

Provides increased access and support to core facilities campus-wide

Key Components:

• Biomarkers Core (human & clinical, mouse, more)
• Clinical Genetics core
• Imaging Core
• Access to and pilot support for additional cores through the Herbert Irving Comprehensive Cancer Center: confocal microscopy, flow cytometry, genomics technologies & cytogenetics, proteomics, metabolomics
LOOKING FOR CORE RESOURCES FOR TRANSLATIONAL RESEARCH?
Requesting a consultation or access to a resource
Transgenic Mouse Database

Welcome

The Columbia University/Irving Institute Transgenic Mouse Web site is a UNI-protected searchable database for transgenic mice hosted at Columbia University. Included are transgenic mice that are unavailable through common distributors and that can be distributed to the Columbia University research community. This system allows users to search by different categories and to add new transgenic mice to the database.

After identifying mice of interest, please e-mail the PI by clicking on the PI's name. If the PI agrees to share mice, please initiate a mouse transfer on the ICM website.

Contact Robert Schwabe to offer comments and suggestions, report problems, or delete a mouse line.

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LOOKING FOR COLLABORATORS?

Columbia University

Find collaborators, grants, and publications at Columbia
## Search Results

**All Matches**

<table>
<thead>
<tr>
<th>Grants</th>
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<tbody>
<tr>
<td>Publications</td>
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<tr>
<td><strong>NEW</strong> Community Organizations</td>
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### Grants

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<th>Grant ID</th>
<th>Title</th>
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<tr>
<td>CDUKE CU11-3549</td>
<td>PK &amp; RELATIVE BIOAVAILABILITY OF A LIQUID FORMULATION OF HYDROXYUREA IN PEDIATRIC PATIENTS WITH SICKLE CELL ANEMIA</td>
<td>Green, Nancy</td>
<td>Apr 2011 - Sep 2017</td>
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<td>1R01 FD003894-01A1</td>
<td>PHASE 2 STUDY OF VITAMIN D FOR TX OF RESPIRATORY COMPLICATIONS IN SICKLE CELLS</td>
<td>Brittenham, Gary</td>
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<td>1R21NR013745-01A1</td>
<td>HYDROXYUREA ADHERENCE FOR PERSONAL BEST IN SICKLE CELL TREATMENT HABIT</td>
<td>Green, Nancy</td>
<td>May 2013 - Apr 2015</td>
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<td>AAP CU13-3408</td>
<td>CAN SERIAL ECHOCARDIOGRAPHY BE USED FOR EARLY DETECTION OF CARDIAC ABNORMALITIES IN CHILDREN WITH SICKLE CELL DISEASE?</td>
<td>Krishnan, Usha</td>
<td>Sep 2013 - Jun 2014</td>
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<tr>
<td>BCS-1225926</td>
<td>DOCTORAL DISSERTATION RESEARCH: BONE MARROW TRANSPLANT PRactices FOR CHILDREN WITH SICKLE CELL DISEASE IN THE UNITED STATES AND FRANCE</td>
<td>Sharp, Lesley Alexandra</td>
<td>Aug 2012 - Jan 2014</td>
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How do you access the CTSA resources or get more info?

Visit our web site:  http://irvinginstitute.columbia.edu

Read more about our resources:

http://irvinginstitute.columbia.edu/resources/resources.html

Fill out the request form on the web site for consultation or more information.