ROADMAP TO RESEARCH

A guide to CTSC resources for planning and implementing your study

Weill Cornell Medical College
Clinical & Translational Science Center
A Multi-institutional Consortium
Since its inception in 2007, the Weill Cornell Clinical and Translational Science Center (CTSC) has leveraged the rich array of resources available to Weill Cornell Medical College, our partner institutions and New York City’s diverse communities to advance our mission of expanding new patient preventative interventions and treatments through translational research.

Supported by a grant award from the National Center for Advancing Translational Sciences (NCATS), the largest federal grant ever awarded to Weill Cornell, the CTSC provides an integrated home for services that benefit the broad needs of investigators engaged in translational research. With this support, the CTSC continues to foster multidisciplinary, multi-institutional collaborative research to yield new, effective patient treatments, educate and mentor the translational research scientists of the future, and enhance health care to the underserved in our surrounding communities.

In this booklet you will learn about the CTSC’s wide range of resources. We hope you will take advantage of this information as you plan your research, and we invite you to contact us to learn more about how the CTSC can help. We look forward to continuing to foster translational research while serving the needs of our research community.

Sincerely,

Julianne Imperato-McGinley, MD
Associate Dean, Translational Research and Education
Program Director, Clinical and Translational Science Center
Abby Rockefeller Mauze Distinguished Professor of Endocrinology in Medicine
Chief, Division of Endocrinology
# Table of Contents

## Funding
Seed Funding .......................................................... 1

## Resources
How Do I Apply For CTSC Services? .............................. 2
Translational Research Support Team .............................. 3
Recruitment .......................................................... 4
Nutrition Research Services ........................................... 5
Clinical and Translational Resources Unit ......................... 6
Research Design and Biostatistics .................................. 8
Biomedical Informatics ............................................... 9
Community Engagement and Research ............................ 10
Research and Scholarly Communication .......................... 11
Regulatory Knowledge and Support ............................... 12

## Collaborating Cores
Specialized Collaborative Cores .................................... 13
Technology Transfer .................................................. 15

## Education
Clinical and Translational Education Program .................. 16
The CTSC offers seed funding opportunities for promising new areas of translational research, especially those involving collaboration between traditionally separate disciplines.

**Pilot Awards - Approximately $50K per year for 2 years**
- Funding is provided for up to two years. Priority is given to proposals with:
  - Emphasis on drug discovery, targeted therapeutics, biomarker or device development and novel technologies
  - Team Orientation
  - Translational focus
  - Pre-clinical studies that have near-term potential to translate into patient-oriented research
  - Clinical trials (phases I & II)

**Community Engagement Awards - $20K per year for 1 year**
- Funding is provided for one year. Priority is given to proposals with:
  - Strong community focus with a clear goal of facilitating the transfer of evidence-based practice
  - Collaboration between the community, CTSC institutions and affiliates with emphasis on comparative effectiveness and health disparities research

[http://ctsc.med.cornell.edu/seedfunding](http://ctsc.med.cornell.edu/seedfunding)
The CTSC offers a variety of services and resources to support clinical and translational research. Investigators may request these resources at any time by submitting an application through our electronic Protocol Authoring and Review system (ePAR).

- **Full Resource Application**: Projects that are requesting CTSC patient care resources and that have not been previously peer-reviewed and approved must submit an application which undergoes full scientific review by the Translational Research Advisory Committee.

- **Expedited Application for Externally Peer-Reviewed and Approved Studies**: Projects with prior external peer review and approval that are requesting CTSC resources must submit an application which undergoes expedited scientific review.

- **Expedited Application for Biostatistics and/or Core Lab Only**: Projects requesting biostatistical, general core laboratory, and/or molecular core services, with or without research data management services, may use the short application with expedited scientific review.

- **Short Application for REDCap (Data Management Services)**: Projects needing ONLY REDCap-based research data management services may use this application with expedited scientific review.

To initiate your CTSC ePAR application, please submit a notification of intent to: [ctsc.med.cornell.edu/Apply](http://ctsc.med.cornell.edu/Apply)

For questions, please contact:

James P Holahan, CCRP
Research Manager
jph2003@med.cornell.edu
646-962-8154
The Translational Research Support Team (TREST) provides guidance and support to investigators who plan to conduct their study with CTSC support. A novel addition to team research, TREST expedites the research process by introducing investigators to the CTSC and all its facilities including its research infrastructure, support services and technical cores. Their ombudsmen-like activities escort the team through the research process, from protocol design to project completion, and initiate the formation of multi-disciplinary team research and facilitate its function. The range of support depends on the investigator’s need and TREST availability.

- The **Research Manager** is the initial contact for investigators who have questions and who need assistance in preparing protocol applications or in carrying out their studies. The Research Manager assists investigators in preparing study documents and provides information about CTSC resources.

- The **Research Study Coordinators** assist investigators with activities ranging from pre-screening of subjects and scheduling appointments to preparing paperwork for the research visit. They work with investigators and CTSC nursing staff to ensure that study procedures are completed as outlined in the research protocol.

- The **Subject Recruitment Specialist** was created in response to investigators’ need for targeted assistance with subject recruitment. Working closely with the CTSC’s Community Engagement component, the Subject Recruitment Specialist utilizes local community networks and other resources to create procedures for the recruitment and retention of specialized patient populations for specific protocols. (See next page.)

[http://ctsc.med.cornell.edu/trest](http://ctsc.med.cornell.edu/trest)
Recruitment

An innovative and extensive community engagement and outreach program designed to access New York City’s large ethnically, racially, and age-diverse patient populations. Recruitment assistance includes:

**Assistance with design and production of materials**
- Flyers, brochures, online marketing tools

**Targeted distribution of materials**
- Specific population groups (i.e. age, ethnicity, clinical diagnosis)

**Community Engagement and Research component**
- Access to health fairs and community events in all 5 boroughs
- Organize speaking engagements for research teams

**Recruitment referral support**
- EPIC Search and Alert

**Social Media**
- CTSC Facebook Page: facebook.com/WeillCornellCTSC
- CTSC Blog: WeillCornellCTSCblog.com
- Twitter: twitter.com/WCMC_CTSC

**Research Match**
- National online volunteer registry

**Passport to Research Booklet**

**CTSC Research Listserv**

**Tracking outcomes for recruitment efforts**

http://ctsc.med.cornell.edu/recruitment
This component is capable of implementing a number of nutrition research methods in support of clinical investigations. The manager and senior dietitian are experts in nutrition research design and methodology and serve as consultants and collaborators to clinical investigators within the CTSC community.

**Research Method Services**

- Nutrition research design consultation
- Anthropometric measurements (e.g., skin fold, muscle)
- Bioelectrical impedance measurement (of body composition)
- Indirect calorimetry measurement (of energy requirement)
- Dietary assessment (individuals and groups)
- Research diets; including weighed, controlled, and balanced diets
- Computers with nutrient analysis programs to facilitate diet planning
The Clinical and Translational Resources Unit (CTRU) is a network of resources and facilities. The inpatient and outpatient units are designed to provide a wide range of services including patient monitoring and education, blood drawing and specimen collections, administration of chemotherapeutic infusions, and dispensation of drugs.

Facilities
- **Adult Inpatient Unit**, Payson 2 Pavilion, consists of six rooms with nine beds, nursing station/nurse manager’s office, metabolic kitchen
- **Adult Outpatient Unit**, F260-F263, consists of six examination rooms, study room for continuous infusion studies, and a spacious reception area
- **Pediatric Inpatient Unit**, Greenberg 6 North, consists of six rooms with eight beds and an inpatient procedure/treatment room
- **Pediatric Outpatient Unit**, Helmsley Tower HT3, consists of dedicated space for study visits, a waiting room, and conference room

Staff
- **Research Nurses and Technicians** for adult and pediatric studies carry out the research protocol, ensuring proper and complete clinical implementation while providing research participants with the highest standard in quality.
- **Research Coordinators** assist the investigator with activities ranging from pre-screening of subjects and scheduling appointments to preparing paperwork for the inpatient or outpatient visit. They work with investigators and CTSC nurses to ensure that study procedures are completed as outlined in the protocol.
- **Research Subject Advocates (RSAs)** work with investigators and CTRU staff to promote the safety and rights of research participants.

http://ctsc.med.cornell.edu/patientcare
General Core Laboratory
Vital to the translational researcher, assays performed in this Core are intended to complement procedures undertaken by the investigator and often are neither available in the hospital clinical laboratory nor conveniently available elsewhere. The Core Lab also develops new assays and can adapt already established assays to the requirements of a specific clinical research protocol. Occupying 2,200 sq.ft., it offers methodologies in RIA, ELISA, and multiplex analysis. The lab also offers immunodiagnostic and chemical assays as well as spectrometry equipment available for investigator use. The lab director is available to discuss the feasibility of performing any assay required by a CTSC protocol. The lab also provides:

- Sample processing and storage
- Bulk immunodiagnostic and chemical assays
- Multiplex assay instrument (SECTOR Imager 2400)

http://ctsc.med.cornell.edu/generalcore

Molecular Core Laboratory
Investigators are provided with or trained in the following services for CTSC approved protocols:

- Oligonucleotide synthesis
- DNA sequencing
- DNA, RNA, and protein isolation
- Genotyping
- Quantitative PCR and RT-PCR
- Gene expression profiling
- Western blot analysis
- ChemiDocMP Imaging instrument

http://ctsc.med.cornell.edu/molecularcore
This component was designed to support a large number of trans-institutional projects encompassing a broad spectrum of disciplines. Its principal objective is to provide biostatistical resources for the design and conduct of studies through the integration of the diverse statistical resources already available across the partnering institutions. The specific aims of this component are to:

- Provide a scientific and administrative structure that supports investigators from diverse backgrounds.
- Provide high-quality consultation in research design and biostatistical analysis.
- Train and mentor laboratory and clinical investigators in the quantitative aspects of research.
- Support methodological research for development of novel research design, advancement of efficient analysis methods, and enhancement of statistical software.

**Services Offered**
- Study Design and Proposal Development
- Implementation and Study Conduct
- Data Management
- Data Analysis
- Presentation/Publication

[http://ctsc.med.cornell.edu/biostatistics](http://ctsc.med.cornell.edu/biostatistics)
Biomedical Informatics

The Biomedical Informatics Component provides information technology, services and training to assist in conducting your research through data collection, data integration, analysis, and collaboration and recruitment.

- **REDCap (Research Electronic Data Capture)** provides a secure method to collect and manage data for single-center and multi-center studies. The tool facilitates import and export of data from a variety of statistical tools, as well as enables the production of online surveys to collect data directly from research participants. ([http://ctsc.med.cornell.edu/redcapinfo](http://ctsc.med.cornell.edu/redcapinfo))

- **ARCH (Architecture for Research Computing in Health)** is a new database technology that assists with integrating large volumes of data across studies and diverse sources, including inpatient and outpatient settings. The software enables management of data in a customized database to meet local needs, while drawing on centralized services, standards and governance. This technology is intended for large-scale projects and requires strong local support as well as approval by a central review committee.

- **GobyWeb** is a user-friendly web-based platform developed through a CTSC grant for analysis of high-throughput sequencing data. The technology provides a collection of integrated tools running on a cluster of servers to provide rapid alignment and efficient analysis. The system enables online analysis of hundreds of samples in consistent ways and streamlines processing of RNA-Seq, Methyl-Seq, RRBS, or DNA-Seq datasets. The platform can assist research teams with processing and sharing of results and can be extended for new kinds of analyses.

- **VIVO** is a research networking system, developed through an American Recovery and Reinvestment Act grant awarded to the CTSC, which supports collaboration and dissemination among investigators within and across institutions. The tool is used by more than 100 organizations in over 30 countries. Investigator profiles are created automatically, drawing on a range of authoritative sources within each institution, particularly for publications. The system enables easy customization of investigator profiles to disseminate information, attract students, establish new scientific collaborations, and assist with preparation for annual review of faculty.

[http://ctsc.med.cornell.edu/biomedicalinformatics](http://ctsc.med.cornell.edu/biomedicalinformatics)
The Community Engagement and Research Component serves as the link between the communities of New York City, investigators and community based research and outreach activities. This component has the goal of building long term relationships with communities throughout NYC to disseminate health information, increase awareness about clinical research and increase the representation of underserved and minority groups in clinical research. To assist investigators, this component provides a variety of services which include:

- Promotion of research studies and recruitment of study participants from minority and other underrepresented communities. Our Community Interactive Videoconferencing (CIVIC) program and Heart to Heart Community Outreach free health screening program, for example, provides investigators with the opportunity to educate underserved communities and promote their research studies.

- Support for community based research studies in partnership with the Translational Research Support Team (TREST)

- Assistance with the design and implementation of community based research protocols to ensure best practice measures in research.

- Connecting investigators to resources and other programs at our partner institutions including the Cornell University Cooperative Extension, Hunter School of Nursing and Hunter School of Public Health. For further details please contact us.

- Seed funding grants for community outreach projects through our Community Engagement Awards.

- Seed funding provided directly to community organizations through community initiated planning grants.
Manuscript Editing Services
The CTSC offers editorial consultation services to assist investigators with their writing needs. Services include manuscript editing and proofreading, document-styling guidance, writing advice, and publication planning.

http://ctsc.med.cornell.edu/manuscriptediting

Translational Research Librarian
A specialized translational research librarian is available through the CTSC to assist investigators in gathering preliminary study information from peer-reviewed databases. The CTSC translational research librarian also offers consultation, training, and research support in biomedical informatics. Services include:

Research Development Support
- Comprehensive literature and database searching
- Translational, comparative-effectiveness and community research resources
- Research and teaching portfolio
- Biomolecular data discovery
- Systematic review support

Publishing support
- Custom journal recommendations and impact factors
- Manuscript guidelines and standards
- Copyright and Intellectual Property Rights
- NIH Public Access Policy compliance

Education Support
- Discipline-specific educational resources
- Student-focused information resources assistance and training
- Information literacy

Classes and consultations
- Customized consultations on biomedical informatics research databases, NCBI resources, searching citation databases, bibliographic management tools, publishing, presenting, and biomedical writing.

http://ctsc.med.cornell.edu/scholarlycommunication
The tripartite mission of this component is Support, Integration, and Education. The CTSC provides direct support, assistance and consultation to the research community to share best practices; to develop innovative programs to streamline the regulatory processes needed to facilitate translational research between and among participating institutions; to strengthen subject safety and autonomy; and to improve and expand training and educational programs available to the research communities in general and in the CTSC in particular. It provides:

• **Support**: Regulatory and compliance support, including one-on-one consultation and assistance to the CTSC researcher and research teams in order to satisfy regulatory obligations and reduce the researcher’s regulatory burden.

• **Integrate**: Enhance cooperation and streamline processes between and among collaborating institutions and their regulatory oversight committees, while ensuring that the rights and welfare of all research subjects and the integrity of the data are protected.

• **Educate**: Develop and deliver integrated education and training for researchers, faculty, staff, trainees, subjects, regulatory committee members, and the public served by our partner research institutions on the issues related to the Responsible Conduct of Research.

http://ctsc.med.cornell.edu/regulatoryknowledge
**Specialized Collaborative Cores**

**Citigroup Biomedical Imaging Center (CBIC)**

The CBIC is a state-of-the-art imaging research facility. Major equipment includes two 3.0 Tesla magnetic resonance imaging and spectroscopy (MRI/MRS) systems for human subjects; a 7.0 Tesla/30cm bore preclinical and specimen MRI/MRS system; a combined positron emission tomography and computed tomography (PET/CT) system for human subjects; a preclinical combined PET, CT, and SPECT system; a multispectral optical imaging system, two ultrahigh resolution preclinical and specimen CT systems, a medical cyclotron facility for production of radiotracers; and comprehensive radiochemistry laboratories for ligand synthesis. The Center has been carefully designed to facilitate complementary and integrated use of all imaging modalities.

**Research Facilities**

- 3.0 Tesla Human MRI (2)
- 7.0 Tesla Preclinical and Specimen MRI
- Human PET/CT
- Preclinical PET/CT/SPECT
- Ultrahigh Resolution Preclinical and Specimen CT (2)
- Cyclotron and Radiochemistry Facilities
- Optical Imaging
- Laboratory Facilities

[http://www.weill.cornell.edu/research/cbic/index.html](http://www.weill.cornell.edu/research/cbic/index.html)

**Cornell Ithaca Cores**

- Genomics resources
- Nanobiotechnology

**Hospital for Special Surgery Cores**

- Musculoskeletal repair and regeneration
- Confocal microscopy
Specialized Collaborative Cores

Memorial Sloan-Kettering Cancer Center Cores

• High Throughput Screening helps investigators develop new chemical probes to elucidate novel pathways and provides capabilities to interrogate gene function to discover targets or validate candidate genes.

• Organic Synthesis designs and executes efficient and economical chemical synthesis of entities or compounds not readily available.

• Anti-Tumor Assessment provides evaluation of agents with potential therapeutic activity. Establishes in vivo mouse models; designs and executes pharmacokinetic, toxicity, and in vivo efficacy studies; and determines the best formulation, administration route, and treatment schedule for each new compound, either alone or in combination with other agents.

• Proteomics & Microchemistry performs mass spectrometry based sequence analyses of proteins and peptides; generally for identification, relative quantitative analysis, and post-translational modification (PTM) analysis, and synthesizes and purifies custom peptides up to 50 amino acids in length.

• Pathology (Histology, Immunohistochemistry, Tumor procurement / Banking) provides expertise in pathology, appropriate samples and tissue-based experimentation.

• Mouse Genetics supports the use of genetically manipulated mice for in vivo studies of gene function in biological processes. Relevant fields where mouse models can be applied include cell growth and behavior, cellular differentiation, embryonic development, immunobiology, genome integrity and a variety of disease states.

• Animal Imaging provides investigators with unique capabilities for noninvasively detecting, localizing, and biologically characterizing primary and metastatic cancer cells in vivo in small-animal (rodent) models, including xenograft, transgenic, and knock-out tumor models. This is accomplished by monitoring of “directly-targeting” probes and by expression of single and multi-modality reporter genes using imaging.

http://ctsc.med.cornell.edu/specializedcores
The principal objective of the Technology Transfer component is to promote innovation and facilitate public access to inventions and discoveries resulting from translational research at partnering institutions. It ensures that promising ideas and innovative projects developed under the auspices of the CTSC are appropriately protected as they enter the clinical/translational pipeline.

The Technology Transfer offices of the five partnering institutions work together to annually review novel technologies and select awardees with projects that offer the most translational promise.

Its specific aims include:

- **Promotion** of the generation of novel ideas by enhancing inter-institutional and interdisciplinary communication in unique ways, particularly through the adaptation of the concept of speed networking for inter-institutional multidisciplinary investigator collaboration.

- **Support** for the development of novel ideas in translational methodologies through the development of an “Innovation Incubator.”

- **Education** in patenting, entrepreneurship and drug development to provide hands-on learning about intellectual property and technology transfer such as commercialization and funding opportunities (Small Business Innovation Research (SBIR), Small Business Technology Transfer Research (STTR), venture capital, and angel funds).

http://ctsc.med.cornell.edu/technologytransfer
Clinical and Translational Education Program (CTEP):

- One-year Advanced Certificate in Clinical and Translational (C/T) Investigation
- Two-year Master’s Degree Program in C/T Investigation
- Certificate in Clinical Research Methodology
- CTSC Skills Acquisition Workshops
- Specialized Interactive Workshops in Drug Development
- Career Enhancement Audit track

CTEP offers two training awards which combine mentorship and classroom training, with salary to support protected time for research.

**TL1 Training Award** – approximately $27,000 per year (pre-docs), $62,000 per year (post-docs), 2 years
- Supports early career development and provides advanced degree training and practical skills to conduct interdisciplinary C/T investigation in a team research environment. Trainees pursue research training at 100% time and effort. They receive:
  - Stipend coverage at the NIH approved rate
  - Funding for supplies, research support, educational expenses
  - Funding for travel to present at conferences
  - Access to resources for conducting C/T research, multi-level mentoring, and career development

**KL2 Scholars Award** – approximately $80,000 in salary support per year and $12,000 for research expenses, 2 years
- Provides post-docs (junior faculty, senior residents and fellows) protected time to pursue advanced training and practical skills to conduct multidisciplinary C/T research in a team environment. Scholars pursue research at 75% protected time. Through this program, KL2 Scholars will be prepared for long-term careers in C/T research and develop into independent researchers.

[http://ctsc.med.cornell.edu/education](http://ctsc.med.cornell.edu/education)
The CTSC was initially funded in 2007 and renewed in 2012 through the Clinical and Translational Science Award (CTSA), the largest federal grant ever awarded to Weill Cornell. It has brought to fruition the integration of inter-institutional resources among its neighbors and partners in the immediate area.

- Weill Cornell Medical Center (WCMC)
  - Weill Cornell Medical College (WCMC)
  - Weill Graduate School of Medical Sciences (WGSMS)
  - Weill Cornell Campus of New York Presbyterian Hospital (Greenberg Pavilion)
- Cornell University - Ithaca
- Cornell University Cooperative Extension in New York City (CUCE-NYC)
- Memorial Sloan Kettering Cancer Center (MSKCC)
- Hospital for Special Surgery (HSS)
- Hunter College of the City University of New York
  - School of Nursing (HCSON)
  - School of Public Health
  - Center for the Study of Gene Structure and Function
- Animal Medical Center and Cornell College of Veterinary Medicine

For questions, please contact:
James P Holahan, CCRP
Research Manager
jph2003@med.cornell.edu
646-962-8154