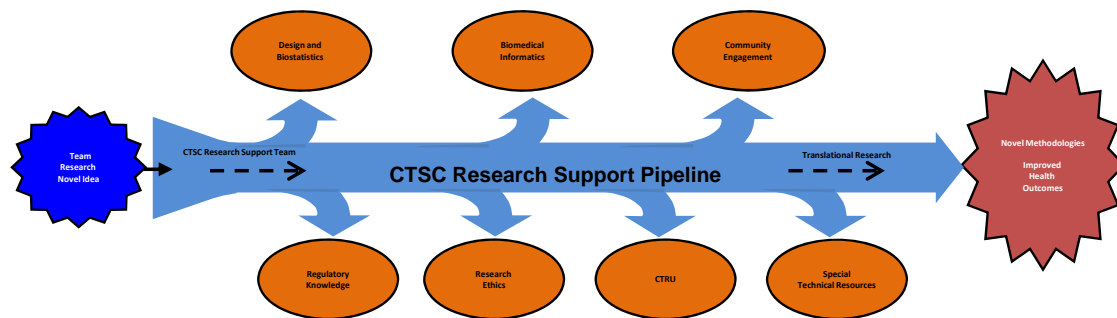


Clinical Research Management and Best Practices



Introduction

The mission is to create a diverse trans-institutional, multi-disciplinary Clinical and Translational Science Center (CTSC), focused on moving translational research seamlessly from bench to bedside and to the community. Weill Cornell Medical College, the lead institution, acts as the conduit and *administrative home* through which essential resources, technological tools and education programs for all partners can be efficiently shared and managed.

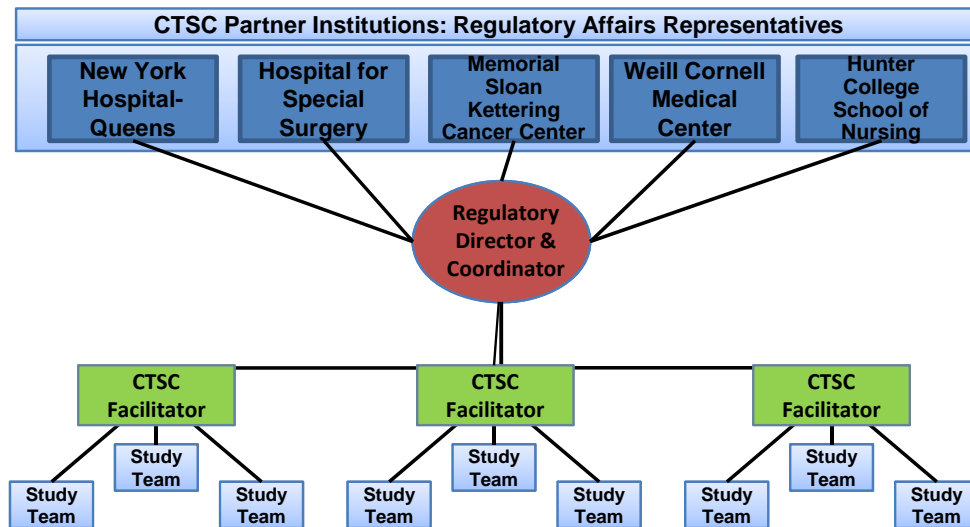
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Partnerships

The CTSC consists of a unique multidisciplinary collaboration between a diverse group of superb centers of intellectual and academic excellence. Led by Weill Cornell Medical College and Weill Cornell Graduate School of Medical Sciences, the new Center also encompasses the Cornell University Cooperative Extension in New York City (CUCE-NYC); New York-Presbyterian Hospital/Weill Cornell Medical Center; Memorial Sloan-Kettering Cancer Center (MSKCC); Hospital for Special Surgery (HSS); Hunter College School of Nursing; The Center for Study of Gene Structure and Function of Hunter College, City University of New York; and an additional six Weill Cornell-affiliated hospitals.

Collaborative studies amongst these institutions are facilitated through a centralized CTSC Regulatory Core (Regulatory Director and Coordinator).



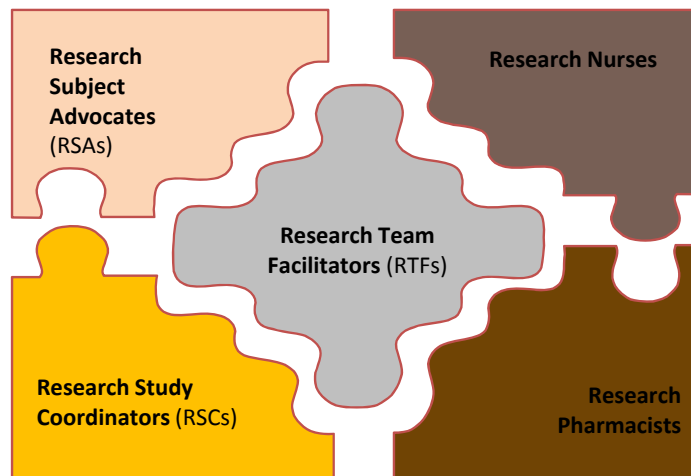
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Research Team Support

At the start of an idea, a Research Team is assembled. Research Team Facilitators (RTFs) lead the team through the research process, from protocol design to project completion; they initiate the formation of multi-disciplinary team research and facilitate its function. They introduce investigators to the center's resources and services to fully outfit a study with the proper tools to carryout best practices and reduce administrative burdens.

Translational Research Support Team (TREST) provides researchers with: (1) support for protocol preparation; (2) data management; (3) research assistance; (4) regulatory compliance; (5) human subject safety monitoring; (6) participant recruitment.



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Study Design and Biostatistics

The Research Design and Biostatistics Core (RDBC) supports a large number of trans-institutional projects encompassing a broad spectrum of disciplines. It provides biostatistical resources for the design and conduct of studies within the Clinical and Translational Science Center. Through the integration of the diverse statistical resources already available across the partnering institutions, this core provides a scientific and administrative structure that supports investigators from diverse backgrounds. Provides high-quality consultation in research design and biostatistical analysis and trains and mentors laboratory and clinical investigators in the quantitative aspects of research; supports methodological research for development of novel research design, advancement of efficient analysis methods, and enhancement of statistical software.

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Protocol Management Tools

ePAR / Webcamp

With the use of the electronic protocol authoring and review (ePAR) secured web-based application, it allows an efficient way to initiate the protocol submission process; flexible support for attached files (e.g., IRB application, consents, etc.); support for revisions, amendments, re-reviews; data on approved protocols transfers over to Census and Protocol Tracking for use in budget tracking, scheduling, etc.



RedCap

The Research Electronic Data Capture System (REDCap) provides a centralized web-based location for data-entry and reporting, with easy user administration and user accessibility.



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A Robust Community Outreach Program

Cornell University Cooperative Extension-NYC (CUCE-NYC) serves as the hub of this initiative.

For over fifty years, its community participation, research and educational programs have extended to underserved and racially diverse populations in all boroughs of NYC.

CTSC Affiliated Hospitals

Seven Cornell-affiliated hospitals, located mainly in underserved areas, provide access to important patient populations that complement those found at WCMC, MSKCC and HSS.

Collectively, these hospitals host specialized programs in HIV/AIDS, substance abuse, asthma, diabetes, low birth-weight babies.

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Facilitating Regulatory Process - the lead institution

The regulatory process is facilitated through integrating resources, enhancing cooperation and streamlining 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. Partner institutions build upon their experience and their history of collaboration, to provide direct support, assistance and consultation to research facilitators and researchers, share best practices and develop innovative programs.

IRB of record – the lead institution

Regulatory review for collaborative studies amongst partner institutions has been streamlined with the lead institution on a study agreeing to be the *IRB of record*. With the implementation of the IRB of record agreement, review boards avoid duplication of efforts, and research collaboration is facilitated.

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Research Ethics

Human subject protection programs must be prepared to meet the challenges posed by this changing landscape, both to educate and support investigators as they design and conduct research, and to protect and advocate for subjects and society. The principal objective of the Ethics Core is for ethicists from partner institutions to work together to facilitate, develop and administer consultative, educational, and research programs across disciplines within the Clinical and Translational Science Center. This allows translational research teams to move beyond the regulatory framework to appreciate the deeper ethical implications of their work for science and the wider community.

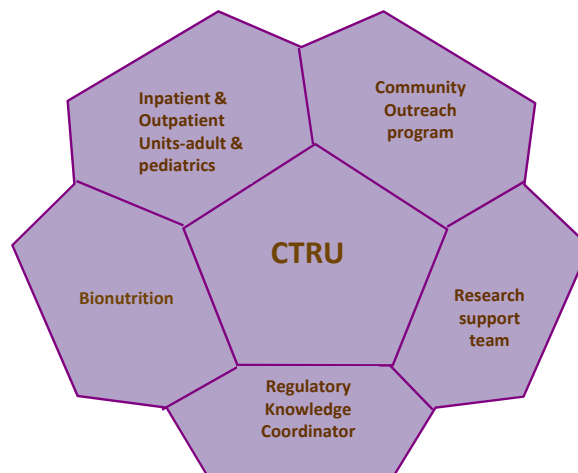
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Clinical Translational Resource Unit (CTRU) – a unit without walls

The CTRU, an expansion of the former General Clinical Research Center (GCRC), is a network of resources and facilities, providing an efficient infrastructure for team research and for the seamless flow of research from bench to bedside to the community. It is the central node of the Clinical and Translational Science Center (CTSC) – the site at which novel lab bench discoveries are ultimately translated to best practices within the community in a team-oriented environment. Forming an integrated, dynamic resource, it includes professionally staffed patient care inpatient and outpatient units for adults and children, and resources and services for conducting scientifically sound studies.

A trans-institutional resource, it will be integrated with partnering institutions and a robust community engagement and outreach program - *a GCRC without walls*.



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Special Technical Resources

Trans-institutional Technological Core Facilities offer specialized tools to assist research teams in the conduct of their projects and are a major part of the CTSC infrastructure. The principal objective of the essential core facilities are to ensure that CTSC translational research teams have access to state-of-the-art technologies that support all stages of the translational research process. They provide quality service spanning participating institutions. The partnering institutions, with their numerous Technical Cores, are well positioned to leverage these assets to facilitate the conduct of translational research within the CTSC. Most of these Cores are on the "The Avenue" making them geographically very accessible to the CTSC community.

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Advantages

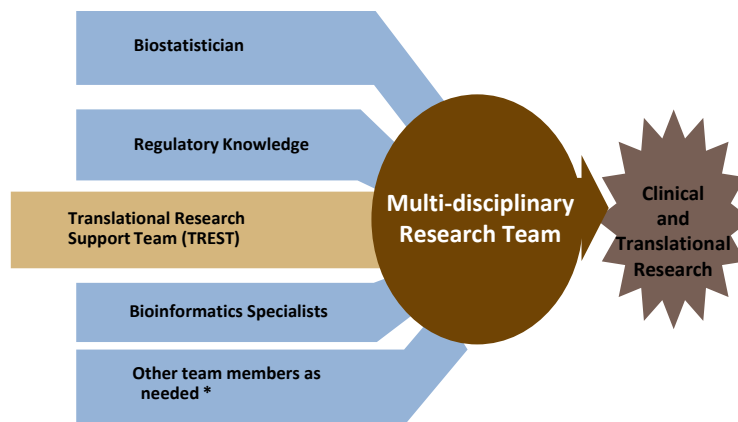
Through the integration of existing inter-institutional resources among neighbors on “The Avenue”, and partner institutions in the immediate area, the resulting cluster of East Side institutions forms a unique and cohesive biomedical complex fulfilling the NIH roadmap initiative of breaking down institutional and disciplinary silos. The partner institutions are committed to this goal. Integration of these unique resources facilitate translation of breakthroughs in the laboratory to clinical research at the bedside and ultimately to best practices within underserved communities, novel methodologies and improved health outcomes.

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Lessons Learned

Challenges to create a swift way to facilitate collaborative studies and combine institutional research programs have been mitigated with the introduction of the Research Team Facilitators and Regulatory Core. The addition of Community Engagement and shared technical resources amongst the partner institutions complete the research support pipeline to move innovation and better health outcomes. Through the WCMC CTSC's design of research team facilitating, investigators are connected with research collaborators to develop a multi-disciplinary team; and better equipped with the support staff, knowledge and tools to carry out their clinical research.



*e.g., nutritionist, epidemiologist, clinical pharmacologist

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