The Ohio State University Center for Clinical and Translational Science

The Ohio State University Center for Clinical and Translational Science (CCTS) was created to improve the quality of care for all patients in the community by developing a transformative clinical and translational science discipline which is at the core of the OSU academic culture. The CCTS is funded by the National Institutes of Health Clinical and Translational Science Award (CTSA), a NIH Roadmap grant that supports the educational programs and scientific infrastructure necessary to meet the CCTS mission to create a new discipline of clinical and translational research. The goal of the CTSA is to speed the translation of new scientific discoveries to enhance patient outcomes.

Local Collaboration
The CCTS leverages expertise from colleges across the University including scientists and clinicians from multiple colleges, primarily the Health Sciences colleges, the OSU Medical Center and Nationwide Children’s Hospital. Rebecca Jackson, MD is the principal investigator of the CTSA; co-principal investigators include John Barnard, MD, of Nationwide Children’s Hospital and William Malarkey, MD. The 10 program directors and their co-directors come from varied scientific and educational backgrounds and include faculty from Medicine, Nursing, Pharmacy, Optometry, Public Health, Veterinary Medicine, Engineering and Dentistry.

National Consortium
The Ohio State University is one of 46 academic medical research institutions working together as a national consortium to improve the way biomedical research is conducted across the country. The consortium, shares a common vision to reduce the time it takes for laboratory discoveries to become treatments for patients, and to engage communities in clinical research efforts. It also fulfills the critical need to train the next generation of clinical researchers. The CTSA initiative is led by the National Center for Research Resources at the National Institutes of Health.

The Ohio State University’s Center for Clinical and Translational Science (CCTS) is located in the Prior Health Sciences Library on the Medical Center’s main campus. The Center houses personnel from the administrative and core support programs. Conference rooms and dedicated space are available to provide educational programs and to promote collaboration and interaction between researchers, trainees and the community.

Administrative Core
Principal Investigator: Rebecca Jackson, MD
Co-Principal Investigators: John Barnard, MD; William Malarkey, MD

The CCTS administrative core integrates Ohio State’s 10 CCTS programs and other clinical research support activities.

The program supports individual investigators by:
• Providing research seminars.
• Hosting an annual Clinical and Translational Science research meeting.
• Identifying mentors for trainees and career development opportunities for faculty engaged in clinical and translational science.
• Developing new research teams.
• Identifying new national funding opportunities for clinical and translational science research.
• Offering research concierge service.
Research Concierge Service

Ohio State’s clinical and translational research capability exists in a complex and decentralized setting that can cause barriers to successful team formation, contribute to delays in implementing research studies, and discourage new and junior faculty from initiating research projects. To facilitate the research process, the CCTS provides a research concierge service. The research concierge has thorough knowledge of the CCTS, Nationwide Children’s Hospital and the University research network, and understands research methods and processes.

The research concierge assists faculty, staff, students and research administrators by:

- Providing guidance in navigating the OSU research infrastructure.
- Assisting with submitting requests for resources and specialized expertise.
- Providing access to requests for applications (RFAs) from a variety of sources.
- Assisting young investigators searching for mentors/potential collaborators.

E-mail: CCTSConcierge@osumc.edu
Resource Request: http://ccts.osu.edu/drupal/ccts-webapps/frontdoor

Biomedical Informatics

Program Director: Phillip Payne, PhD
Program Co-Director: Herb Smaltz, MBA, PhD

Summary of specific aims:

- Provide an informatics-based catalyst for multidisciplinary clinical and translational science endeavors by CCTS participants.
- Provide investigators, trainees and research staff at The Ohio State University and Nationwide Children’s Hospital with access to state-of-the-art biomedical informatics expertise, technologies and data management platforms.
- Leverage the skills and tools that exist within Ohio State’s Department of Biomedical Informatics, the Medical Center’s Information Technology department (OSUMC-IT) and the Ohio Super Computer Center, in order to advance the state of clinical and translational science.

The program supports individual investigators by:

- Conducting informatics requirements analysis and project planning consultations.
- Performing custom research data capture and management application development, including the provision of REDCap and Study Trax electronic data capture tools.
- Developing and managing grid computing infrastructure (TRIAD) components in order to enable distributed query, exchange and dissemination of phenotypic, biomolecular and tissue-anchored data sources.
- Offering comprehensive knowledge management services, including the development, annotation and curation of domain models to support systematic data interchange and semantic interoperability, spanning the clinical, research and educational domains.
- Implementing and supporting research networking systems, including content management systems, Web portals, and team-science collaboration tools, including Microsoft Office Sharepoint Services (MOSS) and Drupal.
- Delivering informatics training and education programs.
- Facilitating access to operational and clinical data from the Medical Center and the Information Warehouse.

E-mail: ccts-informatics@osumc.edu
Resource Request: http://ccts.osu.edu/drupal/ccts-webapps/frontdoor
Community Engagement
Program Director: Mary Ellen Wewers, PhD, MPH
Program Co-Director(s): Kelly Kelleher, MD, MPH

Summary of specific aims:
• Establish partnerships between researchers at Ohio State and leaders and healthcare providers in Ohio communities that promote participatory, community-based research.
• Create a Community Research Leadership Group.
• Establish a Community Engagement Office.
• Build Community Leadership Development Program.
• Foster community research
  • Ensure a productive research environment that is responsive to Ohio’s community needs and aspirations.
• Enhance training methods and tools for current and future researchers.
• Enhance training methods and tools for community residents and organizations.
• Create support structure that helps researchers, community organizations, community residents and community healthcare providers/professionals partner more effectively.
• Facilitate community dissemination and implementation
• Develop Translational Toolkit for investigators building new interventions.
• Create routine communication links with community partners.
• Distribute tools to assess and track improvements in community health care.

The program supports individual investigators by:
• Providing access to grant and study planning, design and analysis support.
• Developing training for clinical and translational researchers in statistical methods, experimental and trial design and scientific inference.
• Assisting the administration of the CCTS in facilitating collaboration.
• Offering ethics consultation.

E-mail: ccts-community@osumc.edu
Resource Request: http://ccts.osu.edu/drupal/ccts-webapps/frontdoor

Novel Clinical and Translational Methodologies
Program Director: Chandan Sen, PhD
Program Co-Director(s): Richard Hart, PhD

Summary of specific aims:
• Enable the identification, generalization, dissemination and adoption of novel clinical and translational meta-methodologies.
• Develop a CCTS-wide inventory of novel methodological expertise, resources, techniques and principles.
• Design, evaluate and model processes by which clinical and translational methodologies may be generalized into meta-methodologies.
• Design organizational, functional, biostatistical and informatics-support mechanisms for the CCTS to facilitate dissemination and adoption processes.
• Develop a content repository and content for the CCTS Web portal that will provide CCTS participants and Clinical and Transitional Science Awards (CTSA) consortium members with access to the research products generated.
• Identify and provide resources to support the in-depth evaluation of research studies and programs involving novel clinical and translational methodologies.
• Target two testbed projects based on laser capture microdissection that have the opportunity to expand and transform clinical and translational science through enhanced phenotyping methodologies.
• Develop and disseminate meta-methodologies derived from CCTS multi-disciplinary projects.

E-mail: ccts-biostat@osumc.edu
Resource Request: http://ccts.osu.edu/drupal/ccts-webapps/frontdoor

Design, Biostatistics and Ethics Support and Training (DBEST)
Program Director: David Jarjoura, PhD
Program Co-Director: Soledad Fernandez, PhD

Summary of specific aims:
• Provide support for design, analysis and proposal preparation to clinical and translational investigators who do not have external funding.
• Provide expert consultation for ethical and regulatory issues for research involving human subjects.
• Provide educational programs on design, biostatistics and ethics.
• Promote the development and implementation of new methods for solving biostatistical or design problems in clinical and translational research that have not yet received common recognition.

E-mail: ccts-biostat@osumc.edu
Resource Request: http://ccts.osu.edu/drupal/ccts-webapps/frontdoor
The program supports individual investigators by providing:

- Seed funding to resident experts on the two stated test-bed technologies: laser capture microdissection and microRNA.
- Laser capture of single cell populations or multicellular structures (e.g. blood vessels) from histological sections.
- miRNA analysis post-laser capture.
- Proteomics analysis post-laser capture.
- Partnership with the Pilot Studies program to fund projects utilizing technologies developed in the above-said testbed programs.

E-mail: ccts-methods@osumc.edu

Resource Request: http://ccts.osu.edu/drupal/ccts-webapps/frontdoor

Participant and Clinical Interactions Resources (PCIR)

Program Director: William Malarkey, MD
Program Co-Director: William Smoyer, MD

Summary of specific aims:

- Integrate and develop the various Ohio State and Nationwide Children’s Hospital-based research sites into an effective human-subject-research unit.
- Provide researchers with a state-of-the-art toolkit for clinical and translational research.
- Foster, promote and monitor protocol development, compliance and subject safety.
- Help investigators recruit and retain subjects for clinical and translational studies.
- Coordinate clinical trials and resources with Nationwide Children’s Hospital.

The program supports individual investigators by:

- Offering assistance during protocol development stage to assure inclusion of multiple strategies for recruitment/retention in initial submission.
- Assisting with recruitment, including brochure design for advertisement, liaison with “ResearchMatch.org” participant registry, introduction to OSU-PCPBRN recruitment sites, and retention strategies.
- Managing CRC clinical chemistry laboratory for human and animal specimen bioassay analysis.
- Assisting with budget development.
- Facilitating access to NCH Clinical Studies Center.
- Providing a research concierge service; CCTSConcierge@osumc.edu.

E-mail: ccts-pcir@osumc.edu

Resource Request: http://ccts.osu.edu/drupal/ccts-webapps/frontdoor
Pilot and Collaborative Translational and Clinical Studies
Program Director: Chanden Sen, PhD
Program Co-Director(s): John Sheridan, PhD

Summary of specific aims:
- Enhance the development of new multidisciplinary scientific teams through pilot funding to support the generation of preliminary data.
- Respond to new scientific opportunities and priorities through targeted pilot RFAs.
- Foster new research efforts in clinical and translational science methodology and technology by supporting new multidisciplinary studies and scientists through pilot funds.

The program supports individual investigators by:
- Awarding pilot funding in Request for Applications (RFA) competitive process.
- Maintaining a directory of available pilot funds from multiple sources on the CCTS Web portal.

E-mail: ccts-admin@osumc.edu
Resource Request: http://ccts.osu.edu/drupal/ccts-webapps/frontdoor

Regulatory Knowledge and Support
Program Director: Michael Para, MD
Program Co-Director(s): Alexander Rakowsky, MD

Summary of specific aims:
- Develop researcher-focused training program on human and animal experimentation that conveys the importance and knowledge of human subject protection and humane methods for using animal models.
- Use online training modules, research town meetings, one-on-one education/training sessions, electronic newsletters and messaging to update Good Clinical Practice and regulatory compliance.
- Establish standardized, tiered training curricula for researchers and staff.
- Complete Association for the Accreditation of Human Research Protection Programs accreditation.
- Provide human and technical support to help investigators fulfill human and animal subject regulatory requirements without the loss of their sense of responsibility.
- Promote the CCTS Office of Regulatory Support to researchers for review and comment on protocol submissions, including those to the IRB or sponsors.
- Consultation on data and safety monitoring plans and processes.
- Expand Research Subject Advocate activity beyond Clinical Research Center protocols to include active participation in IRB-identified protocols, data and safety monitoring committees, or where otherwise requested by researchers.

The program supports individual investigators by:
- Offering technical assistance with protocol submissions, including consultation on consent and HIPAA documents.
- Assisting with data and safety monitoring plans.
- Organizing educational programs in collaboration with ORRP.
- Providing a Research Subject Advocate for all clinical research studies.
- Assisting with Institutional Animal Care and Use Committee (IACUC) protocol submissions.

E-mail: ccts-regulatory@osumc.edu
Resource Request: http://ccts.osu.edu/drupal/ccts-webapps/frontdoor

Research, Education and Career Development
Program Director: Philip Binkley, MD
Program Co-Director(s): Michael Grever, MD (TL1 Training Program); Karla Zadnik, OD, PhD, (KL2 Protégé Program); Ginny Bumgardner, MD, PhD, and Karen Ahijevych, PhD (Research Education Resources and Special Programs).

Summary of specific aims:
- Create a flexible and dynamic curriculum in clinical and translational science.
- Provide research education and resources for all clinical and translational research professionals and team members.
- Support the CCTS TL1 Early Career Development Program in Clinical and Translational Research program.
- Sponsor Careers in Clinical and Translational Science: the CCTS KL2 Protégé Program for Career Scientist Development.
- Develop approaches for recruitment and retention of trainees so that the goal of a diverse biomedical clinical and translational research community is realized.

The program supports individual investigators by:
- Providing clinical and translational research training to postdoctoral trainees through a TL1 award mechanism with stipend and tuition support.
- Supporting junior faculty through a mentored KL2 award program.
- Delivering advanced training and technical assistance for all clinical research-related applications, including the electronic medical record (EMR).
- Offering research education resources and training including workshops, podcasts, online resources, and seminars.

E-mail: ccts-education@osumc.edu
Resource Request: http://ccts.osu.edu/drupal/ccts-webapps/frontdoor
Tracking and Evaluation Unit
Program Director: Allard Dembe, ScD
Program Co-Director(s): Sharon Schweikhart, PhD

Summary of specific aims:
• Develop and implement an ongoing Tracking and Evaluation system within the CCTS to ensure that all of the Center’s processes and activities are meeting specified objectives and timelines.
• Establish a computer-assisted system to track progress toward reaching established milestones for each CTSA functional area and to document accomplishments with respect to streamlining the clinical and translational research process, fostering the development of transdisciplinary research teams and translating research findings to best practices.
• Conduct formal continuous review of evaluation results to provide suggestion for improvement to functional areas.
• Perform periodic surveys of Ohio State researchers to monitor awareness of and satisfaction with CCTS services, and to identify improvement strategies.
• Contribute to National CTSA Consortium objectives by developing and implementing evaluation techniques that can inform national efforts.

The program supports individual investigators by:
• Assessing the efficiency, costs, and effectiveness of projects undertaken within the CCTS.
• Developing systems to track and assess project accomplishments, and offering researchers a portfolio of technical assistance services which include:
  • outcomes assessment, including non-clinical social and economic aspects, and quality-of-life measurement.
  • health economics analysis.
  • survey research, Web-based and non-Web based.
  • healthcare policy analysis.
  • social network analysis.
  • Lean/Six Sigma approaches to process and quality improvement in clinical and translational research.

E-mail: ccts-admin@osumc.edu
Resource Request: http://ccts.osu.edu/drupal/ccts-webapps/frontdoor

Translational Technologies and Core Resources
Program Director: Robert Brueggemeier, PhD
Program Co-Director(s): Lawrence Mathes, PhD, William Gardner, PhD

Summary of specific aims:
• Provide enhancements to the common portal for access and information on current core resources at Ohio State and Nationwide Children’s Hospital, and expand utilization of these cores.
• Develop new translational technologies and core resources.
  • biomedical imaging resource
  • comparative animal core
  • drug discovery and development
  • Center for Patient-Oriented Psychometrics

The program supports individual investigators by:
• Enhancing the directory of Translational Technology Resources (cores) on the CCTS Web portal.
• Establishing a biomedical imaging core.
• Establishing a Translation Technology Resources Oversight Committee.
• Developing and facilitating access to new Translational Technologies cores and expanding resources.

E-mail: ccts-technology@osumc.edu
Resource Request: http://ccts.osu.edu/drupal/ccts-webapps/frontdoor