The Ohio State University Center for Clinical and Translational Science

The Ohio State University has created the OSU Center for Clinical and Translational Science (CCTS) to improve the quality of care for all patients in the community by developing a transformative clinical and translational science discipline that 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 will leverage expertise from colleges across the University including scientists and clinicians from the seven 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 and Dentistry.

National Consortium

The Ohio State University is one of 38 academic medical research institutions working together as a national consortium to improve the way biomedical research is conducted across the country. The consortium, funded through the Clinical and Translational Science Award (CTSA), 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 is also fulfilling 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.

Administrative Core

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

Summary of specific aims:
• Oversee and integrate activities of the 10 OSU CCTS programs and other OSU clinical research support activities to create a discipline of clinical and translational science.
• The program supports individual investigators in Year One by:
  1. providing seminars.
  2. organizing a Clinical and Translational Science Research Forum.
  3. identifying mentors and organizing career development activities to support faculty and trainees engaged in clinical and translational science.
  4. facilitating development of new research teams.
  5. identifying new national funding opportunities for clinical and translational science research.

CCTS Research Programs

The Ohio State University was awarded $34.1 million over five years to develop new programs and enhance existing efforts in 10 key areas:
• Biomedical Informatics
• Design, Biostatistics and Ethics Support and Training
• Regulatory Knowledge and Support
• Participant and Clinical Interactions Resources
• Community Engagement Core
• Pilot and Collaborative Translational and Clinical Studies
• Novel Clinical and Translational Methodologies
• Research Education, Training and Career Development
• Translational Technologies and Core Resources
• Tracking and Evaluation

These areas are the critical component of the CTSA. They work together around the core of the Center comprised of OSU and Nationwide Children’s Hospital’s faculty.

Biomedical Informatics

Program Director: Philip Payne, PhD
Program Co-Director(s): Herb Smaltz, MBA, PhD

Summary of specific aims:
• Develop a grid-computing infrastructure intended to enable interoperability and electronic data interchange between disparate and geographically distributed institutional and community-based translational research data collection instruments, data repositories and analytical services.
• Create a knowledge-management initiative to facilitate semantic interoperability between administrative, basic science, clinical and research computing systems.
• Establish a Center for Translational Research-Computing that will provide translational researchers with a single access point for computing resources and expertise.
• Execute workflow and usability assessment studies to identify gaps in programwide translational research work processes.
• Further develop existing and planned biomedical informatics training initiatives.
• Facilitate a national CTSA-effort to develop, disseminate and utilize grid, large-scale data and high-end computing tools.

The program supports individual investigators in Year One by:
  1. providing consulting services to investigators and research staff in order to assist them in planning for and identifying informatics support and services.
  2. facilitating access to clinical/phenotypic data contained in the OSUMC Information Warehouse.
  3. enabling access to collaborative Web tools intended to support team-science activities.

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Design, Biostatistics and Ethics Support and Training
Program Director: David Aronsky, PhD
Program Co-Director(s): Stanley Lemesnev, PhD

Summary of specific aims:
• Develop efficient and effective mechanism for providing design, analysis and proposal preparation support to clinical and translational investigators who do not have sufficient external funding for such support.
• Develop mechanism of design, analysis and trial oversight support that includes expert consultation for ethical and regulatory issues.
• Provide several highly rated educational programs on design, biostatistics and ethics and continue to investigate new approaches to better reach clinical and translational investigators including venues outside of the traditional classroom.
• Promote the development of new methods for solving biostatistical or design problems in clinical and translational research and support the identification and implementation of innovative methods that have not yet received common recognition in this area.

The program supports individual investigators in Year One by:
1. increasing access to design, biostatistics and ethics support and training.
2. educating clinical and translational researchers in statistical methods, experimental design and scientific inference.

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 GCP and regulatory compliance.
• Establish standardized, tiered training curricula for researchers and staff.
• Complete AAHRPP accreditation.
• Provide human and technical support to help investigators fulfill human and animal subject regulatory requirements without the loss of their sense of responsibility.
• Establish new Regulatory Support Office with the CCTS for technical help on IRB submissions and advice on documentation and monitoring.
• Implement new electronic IRB/IACUC protocols submission software.
• Expand Research Subject Advocate activity to include active participation in IRB-identified high-risk protocols, data and safety monitoring committees.
• Select and implement a clinical trial management system that integrates human subject regulatory activities with subject recruitment, clinical/research care, adverse event reporting, consents, research billing and contracting.

The program supports individual investigators in Year One by:
1. providing technical help with IRB submissions including consent documents and HIPAA forms.
2. providing educational programs in collaboration with ORRP.
3. providing access to a Research Subject Advocate for all clinical research studies.

Participant and Clinical Interactions Resources
Program Director: William Moloney, MD
Program Co-Director(s): William Moyer, MD

Summary of specific aims:
• Integrate and develop the various OSU hospital-based and community research sites into an effective human subjects research unit.
• Provide researchers with a state-of-the-art toolkit for clinical and translational research.
• Foster, promote and monitor protocol compliance and subject safety.
• Help investigators recruit subjects for clinical and translational studies.

The program supports individual investigators in Year One by:
1. providing resources for investigators conducting inpatient and outpatient clinical research.
2. running assays for human and animal specimens.
3. providing access to nursing and biounitrition services for hands-on implementation of clinical research studies.

Community Engagement
Program Director: Mary Ellen Wawers, PhD, MPH
Program Co-Director(s): Kelly Kalkwarf, MD, MPH

Summary of specific aims:
• Community Engagement
  o Establish viable and trusting relationships and partnerships between researchers associated with The Ohio State University and leaders, members and healthcare providers in Ohio communities that transcend existing research agendas and allow for new paradigms regarding participatory, community-based research.
  o Create Community Research Leadership Group.
  o Establish Community Engagement Office.
  o Build Community Leadership Development Program.
• Community Research
  o Ensure greater capacity and a more productive research environment responsive to Ohio community needs and aspirations.
  o Enhance training of and tools for researchers.
  o Enhance training of and tools for community residents and organizations.
  o Create support for researchers, community organizations, community residents and community healthcare providers/professionals to partner more effectively.
• Community Dissemination and Implementation
  o Develop Translational Toolkit for investigators building new interventions.
  o Create routine communication links with community partners.
  o Distribute tools to assess and track improvements in community health care.

The program supports individual investigators in Year One by:
1. awarding pilot funds for community-based translational research studies.
2. providing resource materials for developing community-based studies.
3. providing training opportunities such as a research conference that brings together faculty and community stakeholders.

Community Research
Program Director: William Malarkey, MD
Program Co-Director(s): William Smoyer, MD

Summary of specific aims:
• Create routine communication links with community partners.
• 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 in Year One by:
1. awarding pilot funds for community-based translational research studies.
2. providing resource materials for developing community-based studies.
3. providing training opportunities such as a research conference that brings together faculty and community stakeholders.

Community Dissemination and Implementation
Program Director: Kelly Kalkwarf, MD, MPH
Program Co-Director(s): William Moyer, MD

Summary of specific aims:
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  o Establish viable and trusting relationships and partnerships between researchers associated with The Ohio State University and leaders, members and healthcare providers in Ohio communities that transcend existing research agendas and allow for new paradigms regarding participatory, community-based research.
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Novel Clinical and Translational Methodologies Program
Program Director: Chandan Sen, PhD
Program Co-Director(s): Richard Hart, PhD

Summary of specific aims:
• Develop and disseminate meta-methodologies derived from CCTS multi-disciplinary projects.
• Target two testbed projects that have the opportunity to expand and transform clinical and translational science.
• Enhance the development of new multidisciplinary scientific teams through pilot funding to support the generation of preliminary data.

Research, Education and Career Development
Program Director: Philip Brinkley, MD
Program Co-Director(s): Michael Grever, MD (T32 Training Program); Karla Zadnik, OD, PhD, and Larry Schlesinger, MD (K12 Protégé Program); Ginny Bumgardner, MD, PhD, and Karen Ahijevych, PhD (Research Education).

Summary of specific aims:
• Develop approaches for recruitment and retention of trainees so that the goal of a diverse biomedical clinical research workforce is achieved.
• Establish Careers in Clinical and Translational Science: The CCTS K12 Protégé Program for Career Scientist Development.

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

Summary of specific aims:
• Design and execute organizational, functional, biostatistical and informatics-support mechanisms for the CCTS.
• Develop a CCTS-wide inventory of novel methodological expertise, resources, techniques and principles.
• Enable the identification, generalization and accelerated dissemination and adoption of novel clinical and translational methodologies.
• Develop new translational technologies and core resources.
  - comparative animal core
  - drug discovery and development
  - Center for Patient-Oriented Psychometrics
  - biomedical imaging resource

Pilot and Collaborative Translational and Clinical Studies Program
Program Director: Clay Marsh, MD
Program Co-Director(s): John Sheridan, PhD

Summary of specific aims:
• Develop new translational technologies and core resources.

Translational Technologies and Core Resources
Program Director: Allard Dembe, ScD
Program Co-Director(s): Hagop Mekhjian, MD

Summary of specific aims:
• Provide a common portal for access and information on current core resources at OSU and Nationwide Children’s Hospital and expand utilization of these cores.
• Foster new research efforts in clinical and translational science methodology and technology by supporting new multidisciplinary studies and scientists through pilot funds.
• Support mini-sabbaticals for faculty to learn new technology or methodology from other laboratories (within OSU or at other CTSA-consortium institutions).
• Develop a CCTS-wide inventory of novel methodological expertise, resources, techniques and principles.
• Enable the identification, generalization and accelerated dissemination and adoption of novel clinical and translational methodologies.
• Design and execute organizational, functional, biostatistical and informatics-support mechanisms for the CCTS.
• Develop new translational technologies and core resources.
  - comparative animal core
  - drug discovery and development
  - Center for Patient-Oriented Psychometrics
  - biomedical imaging resource

Tracking and Evaluation Plan
Program Director: Allard Dembe, ScD
Program Co-Director(s): Hagop Mekhjian, MD

Summary of specific aims:
• Implement the OSU CTSA Program Tracking Evaluation Plan Logic Model, including components for structure, process and outcomes to ensure that all CTSA programs are organized, implemented and operating in accordance with established goals and timelines.
• Track progress toward reaching established milestones for each CTSA functional area as defined by accomplishments as needed.
• Collaborate with the National CTSA Consortium to develop a tracking and evaluation plan to assess the attainment of overall clinical and translational science award “high level” goals.

The program supports individual investigators in Year One by:
1. awarding pilot funding in Request for Proposals competitive process.
2. awarding mini-sabbatical funding through Request for Proposal competitive process.
3. establishing a directory of available pilot funds from multiple sources on the CCTS Web portal.

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