The past few years have seen significant progress in the catalytic translation of medical discovery to advance human health. The Clinical and Translational Science Collaborative has made it possible to develop research relationships between investigators within our partner institutions as well as nationally to accelerate research opportunities that will ultimately improve human health.

In 2007, through a $64 million National Institutes of Health Clinical and Translational Science Award, we became part of a new program to accelerate the transition of research ideas to medical applications that Award was renewed in 2012. Today our Collaborative is one of 61 active consortium members across the country fostering this pioneering work. We’ve focused on developing practitioners, tools, and connections in the discipline of clinical and translational science, providing pilot funds for research, training the next generation of researchers, and helping to expedite the implementation of new discoveries into clinical practice. Our achievements have been facilitated by an exceptional level of trust and collaboration among our partner institutions and other organizations, and the talented people who staff them. It’s an honor to work on a project that brings our amazing health care institutions together on behalf of our community.

This document communicates the notable steps we’ve taken toward understanding the underlying elements of disease and recovery so as to devise better preventions, treatments and cures.

We delight in telling our story. We encourage you to connect with us to help make our initiative an even stronger force for accelerating discoveries for better health.

Pamela B. Davis, MD, PhD
Principal Investigator

Richard Rudick, MD
The Cleveland Area Reliant Institutional Review Board (IRB) Review process includes participation by the Case Western Reserve University (CWRU) Social, Behavioral, and Educational Research (SBER) IRB, the Cleveland Clinic (CC) IRB, MetroHealth Medical Center (MHMC) IRB, and University Hospitals Case Medical Center (UHCMC) IRB. The process relies on executed IRB Authorization Agreements (IAA) between the institutions. These agreements document that all applicable human research subjects protection considerations will be made by one Institutional Review Board (IRB), which will be deemed the IRB of record. The IRBs of the other Cleveland area institutions will accept the approval of the IRB of record through the Reliant Review process. The goal is to eliminate duplication of effort and multiple applications for submission of the same protocol, and to encourage scientific collaboration among the affiliated institutions.

What types of studies are eligible for the Reliant Review Process?

Any type of human research study could be eligible for the Reliant Review process. These include but are not limited to investigator-initiated, federally-funded, foundation-supported, industry-sponsored, and non-funded studies.

The fundamental requirement is that a collaborating investigator must be named at each site where the research will occur. It is important for the Principal Investigator at the lead study site to work with the IRB of record throughout the Reliant Review Process to initiate acceptance of IRB approval at each collaborating site.

For further information, contact:
Kathleen Lawry, Director Reliant Review, MetroHealth Medical Center: (216) 778-2077, klawry@metrohealth.org
Kim Volarcik, Executive Director Research Compliance, CWRU: (216) 368-0134, kav6@case.edu

Announcing the Expansion of the CTSC Regulatory Knowledge Support Core

The research infrastructure and services of the CTSC Regulatory Knowledge Support Core has expanded to include the IND/IDE Regulatory Support Core, a comprehensive center that exists to aid investigators during all phases of their protocol life cycle. This core supports research personnel involved in FDA regulated research studies and is vital to the success and overall compliance of IND/IDE protocols. It also features access to the expertise of qualified monitoring staff for study monitoring, strengthening research outcomes and identifying institutional trends.

The core's modular design approach pictured below allows researchers to begin at any point. By reaching sponsor-investigators early in the process of their FDA pathway, sponsor-investigators stand to benefit from the comprehensive services.

The IND/IDE Regulatory Support Core is now available to investigators on a fee-for-service basis. To get started, contact Carolyn Apperson-Hansen, Director of the Research Concierge Service (ctsc-research-concierge@case.edu).

Process Flow: IND/IDE Regulatory Support Core
**PEER Training Program Graduates**

The Prevention Research Center’s Partners in Education, Evaluation and Research Fellows (PEER) graduated on December 9. Join us in congratulating them, and visit them online to learn more about the program and the PEER fellows of 2013.

The PEER Training Program is an 18-month, part-time mentored program designed to increase research partnership capacity in community organizations and facilitate academic/community research partnerships through the training of a selected staff member of that organization. The training incorporates experience with research process and methodology, and develops increased capacity (knowledge, skills, abilities) to implement and evaluate research within their own organizations. The fellows also received training in cultural competency, health literacy, and the social determinants of health. These didactic sessions were followed by a 6-month period dedicated to carrying out a research project with a university partner.

**The Goals of the Program are to:**

- Increase research capacity in community organizations
- Strengthen community organization/academic partnerships
- Facilitate partnered, translational research

PEER is led by the Prevention Research Center for Healthy Neighborhoods at Case Western Reserve University (PRCHN) and funded by a supplemental training grant from the Clinical and Translational Science Collaborative (CTSC) at Case Western Reserve University.

**Public Outreach and Exposure for Your Research via REAL**

Research Education, Awareness & Learning (REAL) is a CTSC program designed to enhance awareness and knowledge of the general public about research participation using examples of completed and ongoing research in Cleveland. Since 2010, the REAL Program has attended over 70 events, speaking directly with more than 4500 individuals about research and research participation.

The program stresses the importance of research volunteering by highlighting a few of the many past clinical research discoveries that have affected our health and lives today. Additionally, the REAL team presents potential participants with examples of actively enrolling studies in which they could participate.
If you would like your IRB-approved research recruitment materials distributed at events attended by members of the REAL team, please contact Mary Ellen Lawless at mel15@case.edu or REAL@case.edu or call 216-778-1304.

Helpful tips for investigators wishing to have their flyers displayed/distributed by the REAL Committee:

1. All flyers or materials must be reviewed and approved by your IRB of Record (Your local or affiliated IRB that will or has reviewed and approve your protocol)
2. The IRB-approved recruitment plan should include a description indicating that the flyer may be distributed at local health fairs and/or community-based events.
3. The following text is an example description that can be included with your submission and existing recruitment plan to inform your local IRB about the distribution of the flyers/materials by the REAL Committee:

   "The flyers (or relevant description of the recruitment materials to be distributed) will be distributed at community events including, but not limited to health fairs, community events, and events attended by the REAL committee or CTSC Sponsored Events."

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Request for Pilot Proposals

CWRU Nutrition Obesity Research Center (NORC)

New Investigators at CWRU are invited to submit applications for pilot projects for potential inclusion in the Nutrition Obesity Research Center Application (November 2014). Successful proposals will be included in the NIDDK NORC Application and will be considered for funding beginning February 2014. For the purpose of this RFP, new investigators are those without current or prior NIH research project support (RO1, PO1, R24) as a PD/PI.

Award Budget Limited to $50,000 Direct Costs.

Proposals must be submitted through WebGrants, must conform to the CTSC guidelines and must include:

1. Cover page listing contact information for PI and faculty collaborators
2. Proposal (5 pages) in length (excluding references) as follows:
   - Specific Aims (1 page)
   - Background and Significance (2 pages)
   - Experimental Design (2-3 pages)
3. NIH biosketch for all faculty participants
4. Detailed budget in CTSC Format

Preference will be given to proposals that focus on molecular and translational mechanisms, mediators, and modifiers of obesity and related comorbid disorders.

Contact: Lia Chesner, lcc3@case.edu, 368-6457

DEADLINE: Friday, January 17, 2014. Visit the CTSC for details and registration.

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Congratulations to Core Pilot Awardees!

Please join us in recognizing the September and October 2013 CTSC Core Utilization Pilot Award Recipients!

Amit Anand, MD, Cleveland Clinic
"Exploration of pathways underlying the lithium treatment of bipolar disorder"

Neetu Gupta, PhD, Cleveland Clinic
"Target discovery in diffuse large B cell lymphoma using quantitative proteomics"
Daniel Popkin, MD, PhD, University Hospitals Case Medical Center
"Viral replication within professional antigen presenting cells modulates immune response and viral persistence"

Ahmad Khalil, PhD, CWRU School of Medicine
"Identification of differentially expressed lincRNAs in Trastuzumab Resistant Breast Cancer Cells by RNA-seq"

Thomas McIntyre, PhD, Cleveland Clinic
"ADAMDEC1 inhibitor high-throughput screen"

Spring 2014: New Bioinformatics Courses

The graduate program in Systems Biology and Bioinformatics is introducing new courses this Spring to train students, faculty, and staff in bioinformatics and clinical informatics:

SYBB 411: "Survey of Bioinformatics" is being offered in two, month-long modules covering technologies and programming techniques in bioinformatics.

SYBB 422: "Clinical Informatics, Part II" will introduce students to the uses of large healthcare datasets in public health, focusing principally on drug surveillance, comparative effectiveness research, and personalized medicine.

Fliers and syllabi can be found on the course website. Please email Dr. Vishal Patel for more information: vishal.patel2@case.edu.