directors’ perspective
We’ve recently completed our Annual Progress Report to the NIH/NCRR, through which each member of the CTSA, a national consortium of medical research institutions, reports their progress toward achieving the consortium’s vision of improved health. For our CTSC, this has meant a year focused on growing the research enterprise, developing practitioners and core competencies in the discipline of clinical and translational science, and putting research findings to use in clinical practice. We want to share with you some highlights of our progress in these areas, drawn from that Report.

Growing the research enterprise requires that people understand the benefits of participating in the initiative and the role they might play toward achieving the vision. To that end, we have improved our communications in several ways, including initiation of this newsletter, and by a major revision of our website that is focused on describing our purpose, available funding, and resources. Regular meetings among our core directors have resulted in increased collaboration and problem-solving strategies among the people who manage those resources. A welcome packet for researchers new to the CTSC has been developed and is being shared broadly by our Research Concierge office.

Developing practitioners and core competencies in clinical and translational science is an effort that involves not only communications, but education, advocacy, involving clinicians in practice-based research, and much, much more. Our KL2 Scholars Program, which we talked about in our last newsletter, is one of which we are most proud, and we expect it will serve as a national model. Our Practice Based Research Network continues to grow and develop meaningful clinical-initiated projects. Our Community Engagement Core launched training in cultural competency for researchers and continues to engage the community in research design, intervention, and dissemination of information.

CTSC efforts are helping to put research findings to use in clinical practice in many areas. We have previously reported in this newsletter on several programs including diabetes control and intervention in Cleveland’s safety net practices; information and screening for breast cancer to women in a largely uninsured, largely Latina community; and a new case management program grams including diabetes control and intervention in Cleveland’s safety net many areas. We have previously reported in this newsletter on several programs including diabetes control and intervention in Cleveland’s safety net practices; information and screening for breast cancer to women in a largely uninsured, largely Latina community; and a new case management program

As you can imagine, the collaborative efforts of the CTSC are far greater than this column allows us to talk about, but they are important to tell. By summer, we expect to have a more comprehensive report on CTSC achievements to share with you.

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core resources
A wide variety of professionals who hold primary positions in the School of Medicine, The Cleveland Clinic, MetroHealth and University Hospitals, devote a portion of their time to the CTSC. Organized into twelve groups by their area of expertise or interest, these people are at the heart of the initiative. They:

- help design research studies and research tools
- facilitate clinical-investigator interfaces
- facilitate community outreach
- educate everyone involved
- administer and track all CTSC activities.

Featured Core:
Translational Technology Resources

Mark Chance, PhD and Clemencia Colmenares, PhD are Co-Directors of a core group of scientists in a variety of specialties who provides CTSC researchers tools to characterize their clinical populations, understand mechanisms of responses to clinical research interventions, and discover molecular mechanisms underlying disease.

Researchers may access the extensive services of the Translational Technology Resources Core - including accessing archived human subject-derived materials (e.g. DNA, RNA, plasma, serum, urine, tissue blocks) from well defined clinical populations and be able to use core technologies and expertise of the partner institutions - through the Request Management System (RMS) found on the CTSC website under the RESEARCHER tab.

The Translational Technology Resources Core is focused on the development of new technologies where none had existed, as well as finding technologies and facilities that enable clinical and translational research. They provide: Publications and academic training programs in new technologies, mechanisms to enable comparison of data across technological platforms, assistance choosing experiments to address human health questions being investigated that are appropriate to the issues and compliant with Health Information Policy (HIPAA). One example of this sort of work was published in Placenta in 2009*. The Proteomics Core facility was used to screen for protein expression levels in the weak zone of human fetal membranes. Data from this study have led to a greater knowledge of some of the mechanisms that can lead to premature birth.

*Placenta, 30(4):335-41, 2009. PMCID: PMC2693720

Visit our website casemed.case.edu/ctsc/ for more information about the Clinical and Translational Science Collaborative of northeast Ohio.
building collaborations

Responsible research is a primary consideration for every CTSC researcher and activity. Every researcher needs to navigate a host of requirements for ethical research design, institutional and government regulations, participant safety, conflicts of interests, conflict resolution, etc. Navigating their home institution requirements is complex for researchers; undertaking the sort of cross-institutional collaborative studies that the CTSA encourages has been daunting. Working with the CTSC, researchers have access to a well-developed system of assistance with these weighty matters, administered through the Bioethics and Regulatory Knowledge Core Resource. Their work of the past year has focused on strategies to strengthen cross-institutional relationships - especially to increase administrative efficiency and reduce redundancy associated with multi-center research review - with a resultant big win for their efforts.

We are happy to report that a facilitated review process is now in place across CTSC partner institutions: Case School of Medicine, University Hospitals, MetroHealth and the Cleveland Clinic. It is to be used when human subject research is proposed involving two or more CTSC institutions; its structure is based on a similar process used by the National Cancer Institute (NCI) Central IRB model. Essentially, the bulk of the human subject protection considerations will be made by the IRB of record, with secondary review from the IRBs from the associated institutions. The second IRB will retain the ability to accept or reject the initial review, or subsequent reviews, and may require secondary IRB review through the regular means.

This facilitated review process is important to accomplishing the goals of the Cleveland CTSC, which is currently one of only two members of the national CTSA consortium composed of multiple institutions. As clinical and translational research across independent institutions becomes more prevalent, it may also serve as a model for facilitating that important work nationally.

frequently asked questions

Q: What is the new REC Funding Grant?
A: Nearly $8 million in federal stimulus funds is coming to the School of Medicine from the Ohio Health Information Partnership (OHIP). The award, housed at the CTSC, positions the School as a regional extension center (REC) and allows us to help 1,765 health care providers in Lorain, Cuyahoga, Lake, Geauga and Ashtabula counties advance the use of health information technology (HIT) in their practices. The award builds on the recent Center of Excellence designation by the State of Ohio to the School for “Translating Technology and Research into Better Health” which included HIT as a major component.

Q: How do researchers and clinical trials volunteers connect?
A: ResearchMatch.org is a free, secure registry developed by major academic institutions (part of the CTSA) who want to discover knowledge that can have a positive impact on everyone’s future health. It has a simple goal - to bring together people who are trying to find research studies and researchers who are looking for people to participate in their studies. Most research studies need a certain number of people to participate in order to find the right answer. Many of these studies end too early because too few volunteers join. Even though there are many people who want to join research studies, it is hard to find the right match for them or their family. ResearchMatch.org is a new effort to address this problem.

Q: What is the role of the Research Advocate?
A: A Research Subject Advocate (RSA) or a Research Subject Advocacy Program are the individuals or programs that support and ensure the safety of people participating in clinical research. In addition to serving as an advocate for participants, the RSA assists researchers to create a compliant Data and Safety Monitoring Plan and obtain Informed Consent. At the CTSC, RSA’s are part of the Bioethics and Regulatory Knowledge Core Resource; there are RSA’s dedicated to each of the Clinical Research Units housed at the CTSC Partner Institutions - the Cleveland Clinic, University Hospitals, and MetroHealth.

Q: What is “comparative effectiveness”?
A: Comparative Effectiveness Research (CER) is concerned with an evaluation of the impact of different options available for treating a medical condition – between similar treatments i.e. competing drugs or between different approaches i.e. drug therapy or surgery. The federal government has recently taken a stronger interest in CER that ties effectiveness to cost.

Q: How can I learn more about the CTSC?
A: Explore our recently revised website at casemed.case.edu/ctsc. If you are a researcher who has not yet connected to the broad array of services available to you through the CTSC, please read and/or download our Researcher’s Welcome Packet (linked from the homepage). It will give you a very specific overview of how to connect to the CTSC.

ac-ronyms /ˌækroʊˈnɪm/ pronounced [ak-ruh-nim]

- noun 1. a word formed from the initial letters or groups of letters of words in a set phrase or series of words
2. Love them or hate them, we use a lot of them. How well are they understood? Test yourself here.

1. HHS 2. AHRQ 3. ARRA (answers below)