NCRR FACT SHEET

Clinical and Translational Science Awards

www.ncrr.nih.gov/CRctsa
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A national consortium, funded through Clinical and Translational Science Awards (CTSAs), is transforming how clinical and translational research is conducted at academic health centers across the country. Ultimately, this consortium will enable researchers to provide new treatments more efficiently and quickly to patients.

The CTSA program—led by the National Center for Research Resources (NCRR)—will create a definable academic home for the discipline of clinical and translational science at institutions across the country. To create this home, the program allows for local flexibility so that each institution can determine whether to establish a center, department or institute in clinical and translational science. It is here that the next generation of clinical and translational researchers will be trained.

Currently, the consortium comprises 38 academic health centers in 23 states (including 14 centers added in May 2008). When fully implemented in 2012, approximately 60 institutions will be linked together to energize the discipline of clinical and translational science. The consortium is designed to:

- Provide enriched resources to educate and develop the next generation of researchers trained in the complexities of translating research discoveries into clinical trials and ultimately into practice;
- Design new and improved clinical research informatics tools for analyzing research data and managing clinical trials;
- Support outreach to underserved populations, local community and advocacy organizations and health care providers;
- Assemble interdisciplinary teams that include biologists, clinical researchers, dentists, nurses, pharmacists, biomedical engineers and veterinarians; and
- Forge new partnerships with private and public health care organizations, including pharmaceutical companies, the Veterans Administration hospitals, and health maintenance organizations as well as state health agencies.

More information can be found on the NCRR Web site at: www.ncrr.nih.gov/CRctsa.
For more about the consortium, visit CTSAweb.org.

Key Elements of CTSAs

Development of Novel Clinical and Translational Methodologies: To sustain intellectual exploration, faculty members may pursue their funded research in areas such as new phenotyping methods that are more objective and quantifiable, the development of biomarkers for research purposes, clinical trial design research, clinical informatics for longitudinal studies, development of research devices and methods that could be used in patients' homes, predictive toxicology in human populations, and ethics research specific to populations rather than specific trials.

Pilot and Collaborative Translational and Clinical Studies: CTSA support may fund pilot and collaborative clinical research projects that allow clinical and translational trainees or researchers to generate preliminary data for submission of a research grant application; seek to improve clinical design, biostatistics, clinical research ethics, informatics, or regulatory pathways; develop new technologies; or activities defined by the applicant.

Biomedical Informatics: The effective implementation of this program depends largely on communication within centers, departments, or institutes and with all collaborating organizations. Internal, intra-institution, and external interoperability is imperative to allow for communication among these centers, departments or institutes and the necessary research partners, such as government, clinical research networks, pharmaceutical companies and research laboratories.

Design, Biostatistics, and Clinical Research Ethics: Research in these three areas is quite limited, so applicants are encouraged to develop innovative and creative research programs that bridge these functions with other CTSA activities. Topics for research include limiting risk to participants, preventing bias, improving enrollment, capturing appropriate data, developing design and analysis plans for studies of unique populations or very small numbers of subjects, informed consent, and issues related to diseases with limited treatment options.

Regulatory Knowledge and Support: Support for research teams promotes the protection of human subjects and facilitates regulatory compliance. Innovation at all levels of clinical research regulation is imperative, including the provision of integrated training, services or tools for protocol and informed consent authoring and translation, adverse event reporting, safety and regulatory management and compliance, and related activities. Institutions are developing best practices that reduce or remove institutional barriers to clinical and translational research and, through dissemination and sharing, enhance inter-institutional collaborations.

Participant and Clinical Interactions Resources: These resources provide an environment to promote participation in clinical and translational research and help determine the most efficient and effective ways to interact with participants in clinical trials. Examples of resources include the recruitment of research participants; the provision of inpatient, outpatient or community-based exam rooms; medical vans; temporary research participant recruitment/enrollment sites; research nurses; research coordinators; phlebotomists; scheduling services; and services for research specimen collection and shipping. CTSA institutions recruit investigators, especially those early in their professional careers, and make the availability of participant and clinical interactions resources known throughout the institution and medical region.

Community Engagement: The intent of this component is to foster collaborative partnerships and enhance public trust in clinical and translational research to facilite the recruitment of research participants from the community. Approaches include engagement of both the public and community providers, and establishing long-term relationships with community-based groups such as voluntary and professional organizations, schools, women's health groups, faith-based groups and housing organizations. Resources might include community outreach and cultural sensitivity training for institutional clinical and translational researchers, community and provider education and outreach, development of software to facilitate the collaboration of community practitioners, and communication outlets, such as newsletters and Internet sites.

Translational Technologies and Resources: Depending on the needs of the centers, departments or institutes, resources such as mass spectrometry, imaging, ultrasound, positron emission tomography, gene expression, proteomics and translational cell and gene therapies are supported.

Research, Education, Training, and Career Development: A key component of a CTSA is one or more graduate degree-granting and post graduate programs in clinical and translational science. Centers, departments, or institutes will train investigators from diverse disciplines, such as medicine, pediatrics, surgery, dentistry, nursing and pharmacology, as well as study coordinators, project managers and other key clinical research personnel relevant to clinical and translational sciences. Topics include clinical research design, epidemiology, biostatistics, pharmacology, biomedical informatics, ethics, behavioral science, engineering and law.

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National Center for Research Resources

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