Fact Sheet: NIH Clinical and Translational Science Awards (CTSA)

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Need for Change

Clinical and translational research is critical to improving human health. Finding cures and treatments for diabetes, Parkinson's and Alzheimer's diseases, AIDS, cardiovascular disease, inherited disorders, and hundreds of other diseases and conditions will rely on the work of clinical and translational researchers. However, the ability to conduct this research has become increasingly difficult.

In an attempt to address the concerns the research community has raised about clinical and translational research, the NIH has funded facilities, resources, or both to bolster clinical and translational research, such as General Clinical Research Centers, grants for individual or institutional training and mentoring, support for disease-specific centers, clinical trial networks, and training of generations of translational scientists. However, concerns persisted in the research community that clinical and translational research needed greater attention.

NIH Response: Institutional CTSA

To address the need for better integrated and focused clinical and translational research support, NIH is announcing a Request for Applications (RFA) to launch a novel program that will fund Institutional Clinical and Translational Science Awards (CTSAs.) Through these awards, academic health centers may propose transformative efforts appropriate to their own institutions. The RFA was formulated after soliciting input from the research community through meetings and other forums.

The CTSA will provide a "home" for clinical and translational research science within the academic health centers. This home, which can be a center, department, or institute (C/D/I), is expected to include faculty able to conduct original research, develop graduate and postgraduate training curricula and lead programs that integrate clinical and translational science across multiple departments, schools, clinical and research institutes and hospitals.

In addition to the CTSA RFA, NIH is also issuing a one-time solicitation for planning grants to allow institutions more time to prepare a CTSA application in the future.

Key Elements of CTSA

The CTSA RFA provides the following descriptions and examples to potential applicants--

- **Development of Novel Clinical and Translational Methodologies**: To sustain **intellectual exploration**, faculty members could 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:** An applicant can request support to fund Pilot and Collaborative clinical research projects that 1) allow clinical and translational trainees or researchers to generate preliminary data for submission of a research grant application; 2) seek to improve clinical design, biostatistics, clinical research ethics, informatics, or regulatory pathways; 3) develop new technologies; or 4) others as defined by the applicant.

- **Biomedical Informatics** will be the cornerstone of communication within C/D/Is and with all collaborating organizations. Applicants should consider both **internal, intra-institution and external interoperability to allow for communication** among C/D/Is 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 might 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 in diseases with limited treatment options.

- **Regulatory Knowledge and Support**: Support for research teams will promote the protection of human subjects and facilitate regulatory compliance. Applicants are encouraged to be innovative at all levels of clinical research regulation 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, etc. Institutions could develop **best practices that reduce or remove institutional impediments** to clinical and translational research and, through dissemination and sharing, enhance inter-institutional collaborations.

- **Participant and Clinical Interactions Resources:** These resources could 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 might include the recruitment of research participants, the provision of in-patient, out-patient, 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. Applicants should describe a plan to 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 catchments area.

- **Community Engagement:** The intent of this component is to foster **collaborative partnerships and enhance public trust** in clinical and translational research, facilitating the recruitment of research participants from the community. Approaches could 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 C/D/I, resources such as mass spectrometry, imaging, ultrasound, positron emission tomography, gene expression, proteomics, translational cell and gene therapies could be supported.

- **Research, Education, Training, and Career Development**: A key component of a CTSA will be one or more graduate degree-granting and post graduate programs in clinical and translational science. C/D/Is 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.

For more information, visit the CTSA web site at www.ncrr.nih.gov