

Guidance Relevant to NIH Clinical Translational Science Awards (CTSA) and Cancer Center Support Grant (CCSG) Guidelines

At the Center Director's Retreat in Dallas in November, several concerns were raised about interpretation/expectations of CCSG Guidelines in relation to provisions of the newly announced NIH Clinical and Translational Science Awards (CTSA). The CTSA initiative is a consolidation and evolution of multiple separate programs sponsored by the National Center for Research Resources, and includes the General Clinical Research Centers (GCRCs). The CTSA is intended to complement the extramural programs of other NIH Institutes in creating an academic home for clinical and translational research. Although many Cancer Centers may find that relationships with the CTSA will be similar to those with its predecessor GCRC programs, issues relevant to the CCSG Guidelines may arise in some Cancer Centers based on the proposed structure of the CTSA, the organization of the parent institution, and the organization and functions of the Cancer Center. While specifics will vary by institution, some general guidance is provided below. **As an overriding principle, the Six Essential Characteristics, which serve as the cornerstone of the NCI - Cancer Centers Program, remain paramount.** If you have questions, please feel free to contact our office.

Access of Cancer Centers to Resources Provided by the CTSA

The NCI is a major contributor to NIH Roadmap initiatives and it is anticipated that resources established through the CTSA will be accessible to Centers, as well as to all other disease programs within the institution. This is similar to the relationship between Cancer Centers and existing GCRCs, where often cancer clinical research accounts for a significant volume of the Institution's GCRC research portfolio.

Integration of Resources

Resources of the CTSA and other NIH-funded Centers are expected to integrate to the extent possible. Under the September 04 CCSG guidelines, Cancer Centers have the option of accessing institutional cores for services required by CCSG members, and review criteria for this are already in place. Appropriate data must be available at the time of a competing renewal application to ensure that peers can evaluate the shared resource in relation to these review criteria.

The CCSG may continue to provide funding for institutional core services to subsidize cancer center member rates and supplement staffing and equipment costs for special research needs of cancer center members. In general, the CCSG should not duplicate institutional resources that are accessible and appropriate for center members, or support services that are offered to other institutional investigators free of charge.

If proposed institutional shared resources are not structured to meet cancer center needs, in relation to timing or extent or type of services required, separate cores may be supported through the CCSG. They must, however, be rigorously justified at the time of competing renewal.

CCSG Budgeting Issues

Center directors have considerable flexibility under the CCSG Guidelines to move funds between budget areas in response to changing needs and research opportunities. The center director may increase any budget category rated at least excellent in peer reviewers by as much as 25% over the level approved by peer review without prior NCI approval. Rebudgeting of funds into areas rated less than excellent requires NCI approval. If an institutional CTSA core is funded and will serve the needs of center members, funds invested in duplicative cancer centers cores may be rebudgeted under the above guidelines and in accordance with other provisions of the NIH Grants Policy Statement.

Protocol Review and Monitoring System

Scientific review, prioritization, monitoring, and closure to trials of cancer center clinical trials **must** continue as a function of the Protocol Review and Monitoring System of the Cancer Center. It is not acceptable for such to be within the purview of the CTSA or any other Center within the parent institution.