

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

Clinical and Translational Science Awards are sponsored by the National Center for Research Resources. CTSA are intended to complement the extramural programs of other NIH Institutes by creating an academic home for clinical and translational research. The vast majority of institutions with CTSA are also home to NCI-designated Cancer Centers and issues relevant to the Cancer Center Support Grant (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. Additional guidance is provided below.

The Six Essential Characteristics

As a set of overriding principles, the Six Essential Characteristics, which serve as the cornerstone of the NCI - Cancer Centers Program, remain paramount.

Protocol Review and Monitoring System

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

Clinical Cancer Research Reporting

Clinical cancer research must be reported through the NCI Clinical Trials Reporting Program, in accordance with NCI requirements.

Shared Resources

- Shared resources established through the CTSA should be accessible to Cancer Center members.
- Cancer Centers may use CCSG funding to support members' access to either institutionally- or cancer center-managed shared resources. *Institutionally- or cancer center-managed shared resources may include those integrated through multiple NIH funding sources, including CTSA.* (Note: Some types of shared resources may be more suitable for integration than others. Integration of clinical functions, for example, should be carefully evaluated to ensure compliance with other Guidelines requirements, including the Six Essential Characteristics for an NCI-designated Cancer Center.)

- CCSG funding should not be used to establish independent, center-managed shared resources that duplicate institutionally-managed resources if the latter provide cost-effective, accessible, quality services and other CCSG-required benefits to center members.
- CCSG funding should not be used to support shared resource services that are offered to other institutional investigators free of charge.
- If proposed or existing institutional shared resources are not structured to meet cancer center needs in relation to quality, accessibility, or extent or type of services required, separate cores may be supported through the CCSG. They must be rigorously justified at the time of competing renewal.
- All full-fledged shared resources (i.e. not developing), whether institutionally- or cancer center-managed, must be peer reviewed prior to any investment of CCSG funds. 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 the CCSG review criteria.
- During a non-competing cycle, centers may rebudget funds from a cancer center-managed shared resource to an institutionally-managed shared resource, in accordance with NIH policies and procedures, so long as the center-managed shared resource received a successful review in the last re-competing cycle.
- CCSG funding for either an institutional- or center-managed shared resource should be proportional to use by peer reviewed investigators within the cancer center, e.g., if the proportion of resource use by cancer center members is 30%, CCSG funding should generally not exceed that level. (Note: If proportional use of the shared resource by cancer center members is very low, centers may wish to reconsider their appropriateness for funding via the CCSG.)
- As per the CCSG Guidelines:
 - CCSG funding supports fixed costs of shared resources (e.g., staffing and minor equipment), whether institutional- or center-managed, and should reduce or subsidize the usage fees charged to cancer center members.
 - Cancer center leadership should participate in facility planning and oversight of CCSG-supported institutionally-managed shared resources to ensure needs of center members will be met.
- Any publications generated with support from CCSG supported shared resources, whether institutional or center managed, should cite the CCSG grant number.

