

UCSF CTSI Clinical Research Services Cost Recovery Initiative

Guiding Principles for Cost Recovery

I BACKGROUND

CTSI Clinical Research Services (CRS) is committed to maintaining high quality core services to support UCSF clinical research investigators while balancing marked increases in demand for its services with anticipated reductions in CTSA funding and annual escalation of salary and benefit expenses. In addition, NIH policies concerning how CRS services will be supported are changing. Historically each NIH Institute paid into NCCR to cover the costs of clinical research services. Currently, the NIH is moving to a model wherein the costs for clinical research services are being increasingly borne by the individual awards of each Institute/Center.

To facilitate this change in funding models, the CRS will work with investigators and departments to determine the full costs of conducting clinical research and to develop strategic approaches that can optimize funding sources for such research activities. The CRS will continue to utilize CTSA funding to subsidize investigator-initiated clinical research that makes use of its core services.

Income generated through the cost recovery mechanism will allow CRS to maintain current services at a level adequate to meet current demands. In addition, CRS will work with investigators to expand services to meet their emerging needs. The CRS will equip investigators with essential tools and critical resources and in return asks that all investigators maximize opportunities to recover costs from available sources of support.

II PURPOSE

- To formalize and standardize the methodology used for preparing CRS protocol budgets
- To clarify how CRS will subsidize full cost rates
- To identify the funding sources available to support research programs and leverage all available sources to fund needed services
- To support prudent resource management

III GOALS

- To effectively communicate the full cost of providing services
- To continue providing high quality services in the face of escalating salary and benefits expenses and reductions in CTSA grant support
- To work with investigators to expand services to meet their emerging needs
- To optimize the use of resources and facilities

IV GENERAL POLICIES

- A. For all studies using CRS services, a comprehensive assessment of the resources needed and an estimate of full cost will be prepared.
- B. Investigators will initially be expected to fund a *minimum* of 40% of full CRS costs for investigator-initiated studies. CRS staff will work with investigators to include these costs in study budgets or identify alternative funding options. CRS will subsidize *up to* 60% of study costs.
- C. Cost recovery procedures, i.e., the procedures used to establish rates, process charges, and collect payments, will be consistent with funding agency policies and/or the specifics of research awards.
- D. Cost recovery policies and recharge rates will be reviewed and adjusted annually.
- E. For multi-year grants, investigators must budget for estimated inflationary increases for CRS resources/services, consistent with funding agency and UCSF budget assumptions.
- F. Charges that are external to the CRS, for example clinical lab tests, radiology, ECGs, etc. will continue to be charged directly to the investigator per current arrangements at each CRS site.

V POLICY FRAMEWORK by FUNDING AGENCY & INVESTIGATOR

Based on funding agency guidelines/restrictions, the study type, and the funding availability, one of the following cost recovery principles will apply:

- A. For studies funded by sources other than industry (e.g., NIH, not-for-profit agencies, intramural awards, etc.), investigators must budget a *minimum* of 40% of CRS costs when the grant application is submitted. Exceptions to this policy are subject to review and approval.
- B. For studies funded by industry, investigators must include 100% of CRS costs when negotiating the budget with the sponsor.
- C. For investigator-initiated, industry involved studies that are partially funded and/or providing the drug or device only, investigators must budget a *minimum* of 40% of CRS costs. Exceptions to this policy are subject to review and approval.
- D. Requests for exceptional subsidies for early career investigators with limited funding or for unfunded pilot studies will be reviewed and considered by the Cost Recovery Oversight Committee on a case by case basis.

VI POLICY APPLICATION GUIDELINES

- A. **EXISTING STUDIES, including Non-Competing Continuations and NEW STUDIES with Previously Secured Sponsored Funding** (NIH, other Not-for-profit Agencies and Foundations)

All existing approved CRS studies currently conducted in the CRS and new studies for which funding has been secured will be “grandfathered” in under the approved protocol

in effect at the time the original budget was developed. Any modifications that require changes in CRS resources will be considered on a case by case basis. CRS full cost budgets may be prepared for these studies to reflect the duration of the study. Meetings may be arranged between investigators and CRS leadership to discuss the full cost budget. In some cases, there may be opportunities to recover a portion of CRS costs, depending upon overall grant funding and budget flexibility. Decisions for cost recovery will be made on a case-by-case basis and formally documented.

B. NEW, REVISED and COMPETING RENEWAL APPLICATIONS (to NIH, other Not-for-profit Agencies and Foundations)

Effective December 1, 2011, investigators who submit new, revised and/or competing grant applications that plan on using CRS resources, will be expected to include CRS costs in their grant budgets. Investigators should work with CRS staff during the grant budget development process to allow for timely costing of the study. Investigators will be expected to budget a *minimum* of 40% of the full CRS costs in their grant applications, and maybe asked to submit funding agency documentation describing the terms and conditions of funding. Any divergence from the approved protocol that requires additional CRS resources may require review by a sub-committee of the CRS Cost Recovery Task Force or a scientific review committee.

VII ADDITIONAL CRS SUPPORT

In addition to providing support as outlined above, CRS will attempt to provide a “safety net” of additional support to cover evolving NIH policy and agency-specific variations in timelines. Specifically, CRS may increase the level of support in the following circumstances:

- Across-the-board reductions in budget at the Council level of review (i.e., mandated x% reduction in budget, but without specifications on where to cut).
- Line-item reductions that affect funding for CRS services.

These situations require additional review including CRS review of the summary statement, notice of award, or other external review documentation.

VIII CRS COST RECOVERY OVERSIGHT COMMITTEE

Requests for additional subsidies in excess of the levels of support outlined in these guidelines will be subject to review by the Cost Recovery Oversight Committee and approved on a case by case basis. Investigators must allow additional time to allow for this review during the pre-award process.