

June 13, 2016

Dear Investigators,

In July 2015 we alerted you to the major changes mandated by The National Center for Advancing Translational Sciences (NCATS), which administrates the CTSA program, and its impact on Clinical Research Services.

What the NCATS Changes Mean

Specifically, these changes mean that support of certain research activities and personnel with CTSA grant dollars is no longer allowed as of July 1, 2016. This includes:

- Rent for research space
- Inpatient or outpatient care costs
- Research nursing
- Study-specific staff
- Research participant evaluations
- Laboratory testing or imaging, and
- Other CRS direct services

Mitigating the Impact of the NCATS Changes Here at UCSF

While these NCATS changes will have effects here at UCSF, we are pleased to announce those impacts will be minimized for two reasons:

- (1) CTSI Funding: The CTSI renewal application submitted last fall in response to Clinical and Translational Science Award (CTSA) (U54) received a favorable score of 16. Based on prior experience this score should be within the fundable range.

- (2) Additional Funding Support: Even though we anticipate CTSI funding, we have taken several steps to address the likely shortfall in order to mitigate the impact of these changes. We are excited to announce that:
 - We've received monetary support from the Chancellor's Office, the UCSF Medical Center, and the UCSF School of Medicine to continue to provide subsidy support while we look for a more sustainable support model.

What does this mean for You?

- The current recharge rates and subsidy will remain in place through August 31, 2016.
- The Clinical Research Services worked with the Campus Budget Office to revise recharge rates, which have not been changed for 3 years, in order to recover our full costs. These revised recharge rates will increase by approximately 15% over current rates for the period of September 1, 2016, through June 30, 2017. We anticipate an average increase of 5% per year thereafter. All studies will be charged the revised rates. This increase in recharge rates is needed to account for inflation. Recharge rates will be revised annually. The schedule of recharge rates is attached.
- As of September 1, 2016 studies that have a signed CRS budget prior to June 30, 2015 will be subsidized at 60% of the revised recharge rate schedule (or in subsequent years the most recently revised schedule) in effect for Clinical Research Services. This subsidy will continue for the project period of the award or contract for the research study.
- Applications for Clinical Research Services with approved budgets on or after July 1, 2015, will be subsidized at 40% of the revised rates for Clinical Research Services starting September 1, 2016. This subsidy will continue through December 31, 2017.
- Industry-sponsored studies will continue to be charged at full cost. Please refer to the revised rates.
- The administrative costs of operating the CRS are paid for by the CTSI grant. These costs are not passed on to investigators, which amounts to a 14% savings.
- While we've made great progress in securing funding, we are still looking for a permanent funding solution to support clinical services after this date.
- Investigators can request an updated budget estimate with the revised recharge rates beginning on July 1, 2016.

Please contact crsbudgetrequest@ucsf.edu if you would like information on how these changes impact the costs for your specific study.

We hope that you share in our excitement about the commitments by the Chancellor's Office, UCSF Medical Center, and the School of Medicine in support of clinical research services during this time of critical need. Be assured that we recognize the importance of clinical research at UCSF. We will continue to look for ways to support and sustain this vital activity.

Sincerely,

Jennifer Grandis, MD
Associate Vice Chancellor for Clinical & Translational Research