

April 27, 2015

Stephen I. Katz, MD, PhD  
Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)  
National Institutes of Health  
21 Center Drive  
Bethesda, MD 20892-2350

Dear Dr. Katz,

The Endocrine Society appreciates the opportunity to provide comments on the Request for Information (RFI) on Core Centers for Clinical Research (CCCR). We are very interested in the integration of core centers with other research support mechanisms to “accommodate the variable needs of NIAMS research areas that differ with respect to investigator community, resource availability, and knowledge depth and breadth.” While we appreciate that the RFI seeks input on a variety of features of core centers, we focus our comments on approaches to integrate the functions of centers with Clinical and Translational Science Awards (CTSAs). Specifically, we recommend that CCCRs become more integrated with CTSAs as part of the overall financial support system for Clinical Research funded by the NIH.

Founded in 1916, the Endocrine Society is the world’s oldest, largest, and most active organization dedicated to research on hormones and the clinical practice of endocrinology. The Society’s membership of over 18,000 includes scientists studying the relationship between bone, muscle and other organ systems. Many of our members conduct clinical and translational research supported by CTSAs, and we are concerned about the long-term sustainability of such projects. Recent changes to the budgetary structure of CTSAs prohibits the use of funds to finance clinical research centers (CRCs). This introduces additional burdens for institutions, which must find new ways to support investigators and critical research support needs such as nursing staff.

Trainees, in particular those funded through K awards, lack the financial resources to contribute to the costs of a shared resource. Critical financial support for trainees, including the 44 NIAMS-supported K23 awardees, has already been compromised by decreased CTSA support. In addition, institutions cannot make long-term staffing decisions for support personnel based on short-term streams, such as R-series grants. Consequently, additional funding streams are needed to adapt to fluctuating shortfalls. As examples, we provide scenarios in the appendix to this letter describing the magnitude of the costs that would normally be used to support junior investigators and other necessary components of CRCs that are no longer covered by the CTSAs. No institutes have offered to increase budgets for their clinical research studies that use CRCs to compensate for diminished NCRR support. The expectation that institutions will pay for costs for research staff in NIH-funded studies is unrealistic.

Efficient and effective support for clinical research centers requires long-term, steady sources of funding. Without stable support, trainees in particular will be unable to fully participate in clinical research funded by NIH. We therefore recommend that NIAMS explore options to integrate CCCRs into the functions of existing CRCs as a way for institutions to adapt to the changing financial



support structure implemented by NCATS while sustaining NIAMS-supported clinical research studies. Thank you for considering the Endocrine Society's comments. If we can be of any assistance in your efforts, please do not hesitate to contact Dr. Joseph Laakso, Associate Director of Science Policy at [jlaakso@endocrine.org](mailto:jlaakso@endocrine.org).

Sincerely,

Lisa Fish, MD  
President, Endocrine Society

### **Appendix: Cost Estimates**

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Case 1: Sample costs for a 2-year pilot study (n=20) by a junior investigator supported by a K23 grant at a human research center:

1. Total Nursing Salaries: \$5,040 - 7800
  - a. Per hour – \$42-65
  - b. 6 hours
  - c. 20 subjects
2. Total Lab Costs: \$39,411
  - a. \$14,098 previously covered by CTSA
  - b. \$25,313 not covered by CTSA
3. Additional Dexa Charges
  - a. \$900

In summary, the total listed cost of the 20 person pilot study attributable to the CTSA is \$48,111. Of these costs, \$14,000 was subsidized for the junior investigator. These costs do not include the costs of the rooms, which may no longer be covered by the CTSA, and they do not include other costs such as processing muscle biopsy samples, medication, or publication costs. The investigator's K23 provides only \$25,000/year for research expenses and use of resources; therefore there is a shortfall of nearly \$9,000 that the junior investigator must make up.

- Case 2: A 200 patient study with 2.5 hours of work per patient  
Total Nursing Support: \$55,000
  - a. Per hour - \$110
  - b. Total hours – 500

Because the CTSA subsidy for the nursing and room costs will be phased to 0 over 3 years, the investigator will need to supply the entire additional cost of \$55,000.