

December 19, 2010

**Position Statement**

The Clinical Research Forum represents the clinical research leadership of our country's premier academic medical centers. The Society for Clinical and Translational Science represents 5,000 members at the major academic medical centers engaged in this research. The Association for Clinical Research Training represents those who focus on the training and career development of clinical and translational researchers. The Society of General Internal Medicine represents 3,000 members who have a focus on health services and clinical research that has impact across all healthcare and public health. The Association for Patient-Oriented Research represents leaders and educators in this area, who have long promoted the advancement of research. Together, we all support the bold vision of National Institutes of Health (NIH) Director Dr. Francis Collins and strongly endorse the recommendation of the NIH Scientific Management Review Board to establish a new National Center to Advance Translational Medicine (NCATS). Our organization memberships share NIH leadership's sense of urgency expressed by patient advocacy groups, biomedical researchers, legislators, and the U.S. public regarding the need to strengthen the national biomedical research enterprise. The urgent need to reduce the time, effort, and costs required to develop treatments and preventive measures, as well as to deploy effective behavioral and technological approaches to critical public health concerns, has united divergent groups who now speak with one voice, calling for change.

Given our organizations' central mission—to alleviate human suffering from disease through more effective clinical research—we believe the creation of NCATS represents a bold, timely, and well-conceived change in approach, one that will provide the leadership and coordination needed to more effectively leverage the NIH's current substantial efforts in partnership with the country's academic health and science systems. Such an enhanced partnership with the NIH would considerably expand our country's capacity to translate scientific advances into better health care. When we consider the rising costs of health care worldwide, the urgent need for the United States to reverse its declining health status relative to other countries, the growing burden of diseases (many marked by dramatic disparities in outcomes), and the aging population, it is clear that this new center represents a unique opportunity for both the NIH and the country to respond more effectively and efficiently to these challenges.


Among the many important issues that NCATS could address are the following excellent opportunities for innovation:

1. Capitalize on the many innovations and best practices that have emerged from the NIH's considerable investments in its Clinical and Translational Science Awards network and the NIH's Intramural Clinical Center by deploying them at the national level;

2. Expand the Rapid Access to Interventional Development program to areas beyond oncology;
3. Leverage the extant resources and structure of the NIH via this new center to provide cost and time efficiencies in performing required chemistry and toxicology for new therapeutics;
4. Streamline, harmonize, and improve the scientific basis of NIH/FDA regulatory interfaces;
5. Focus efforts on standardizing and making more efficient the institutional review board procedures, and contracting requirements of the NIH and its extramural community to produce an effective and efficient national clinical research enterprise;
6. Rapidly incorporate modern informatics capabilities to improve the quality, scope, and efficiency of data collection, and to reduce costly redundancies;
7. Increase the availability of the NIH's intramural Clinical Center to other academic institutions;
8. Engage the biotechnology and pharmaceutical industries and voluntary health organizations/patient advocacy groups in constructive partnerships with the NIH and academic medical centers;
9. Set common standards for conflict of interest considerations and intellectual property negotiations to enable efficient progress on joint development projects;
10. Continue to apply advances in the behavioral and social sciences to the translation of effective health practices and technology applications;
11. Fully develop the evolving national capacity for patient-centered outcomes research, including continuing to develop comparative effectiveness research; and
12. Support the emerging sciences of community engagement and dissemination of innovation as critical elements in translating advances in biomedical research in order to impact the public's health and address the progressive decline in the longevity and functional status of U.S. citizens relative to other nations;
13. Invest in training programs, career development, and education for future generations of scientists who will rigorously investigate and continually improve the processes of clinical and translational medicine and therapeutics.

NCATS represents a unique opportunity to engage and incentivize our country's most promising young researchers from both the basic and clinical sciences to pursue careers in translational science by providing supportive environments for training and career development. Such long-term investments in new talent and ideas are essential to sustaining our country's leadership and innovation in biomedical research. The members of our organizations are committed to supporting and assisting the leadership of the NIH in making this bold vision a reality.

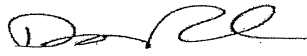
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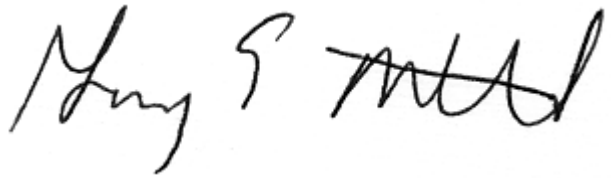
Robert M. Califf, MD, Chairman  
Clinical Research Forum  
1350 Connecticut Avenue, NW Suite 850  
Washington, DC 20036  
(202) 775-0555



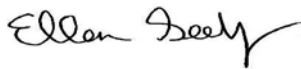
Harry P. Selker, MD, President  
Society for Clinical and Translational Science  
2025 M Street, NW Suite 800  
Washington, DC 20036  
(202) 367-1119



Doris M. Rubio, Ph.D., President  
Association for Clinical Research Training  
1500 Sunday Drive, Suite 102  
Raleigh, NC 27607  
(919) 861-4538



Gary Rosenthal, President  
Society of General Internal Medicine  
2501 M Street, NW Suite 575  
Washington, DC 20037  
(800) 822-3060



Ellen W. Seely, MD, President  
Association for Patient-Oriented Research  
4266 Bell Road, Suite 10  
Newburgh, IN 47630  
(800) 807-6444