ASSOCIATION FOR CLINICAL RESEARCH TRAINING

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A Member Organization of the National Alliance of Societies for Clinical Research Resources (NASCRR):
American Federation for Medical Research (AFMR), Association for Clinical Research Training (ACRT), Association for Patient-Oriented Research (APOR), Clinical Research Forum (CR Forum), Society for Clinical and Translational Science (SCTS), and Society Of General Internal Medicine (SGIM)

Regarding Fiscal Year 2010 Appropriations for Clinical Research Training

Submitted to the
House Committee on Appropriations; Subcommittee on Labor, Health and Human Services, Education and Related Agencies

Wednesday, March 18, 2009, 10:00AM

SUMMARY OF RECOMMENDATIONS FOR FISCAL YEAR 2010:

1) **Works towards fully funding the emerging Clinical and Translational Science Awards (CTSA) Program by providing $573 million in support.**

2) **Continued support for the NIH and AHRQ K-Awards for the training and career development of research scientists.**

3) **Continued emphasis on the importance of Comparative Effectiveness Research (CER) conducting at NIH and the Agency for Healthcare Research and Quality (AHRQ).**

ACRT is committed to improving the nation's health by increasing the amount and quality of clinical research through the expansion and improvement of clinical research training. This training and related career development support comes largely from funds from the NIH and AHRQ.

NASCRR is comprised of the national organizations that provide leadership in the field of clinical and translational research and training. NASCRR coalesces around areas of common concern for the entire biomedical research and training communities and works in support of these goals.

I want to start by thanking the Subcommittee for its strong commitment to improving public health through the recently passed FY 2009 Omnibus Appropriations package and economic stimulus legislation. Both bills provided meaningful funding increases to agencies such as NIH and AHRQ that will translate to improved treatments and health for our citizens. ACRT and NASCRR applaud the Subcommittee for its role in securing this funding, and we hope that this commitment can be sustained and enhanced in subsequent years that should translate into better treatments, healthcare, and health for the US public.

I want to address three issues that are at the center of biomedical research today. First, as is now appreciated by Federal health sciences agencies, Congress, and the new Administration, to gain maximal impact from the nation's investment in biomedical research, there must be a concerted focus on research that translates biomedical science results into improved treatments and more effective healthcare. Second, the past few years have not provided the career development opportunities to generate sufficient well-trained researchers able to do this crucial work. Third, in order to translate the best research results into excellent healthcare, there has to be research that compares the effectiveness of different treatments and for different patients. These three needs are crucial to optimally leveraging the country's investment in research and in healthcare; to not facilitate these is to not to take advantage of the world's greatest biomedical research and medical care capabilities at just a time when we need them.

1) The importance of fully funding the CTSA program.

In the past several years, researchers, the healthcare system, and NIH have come to realize the great need for research focused on translational research – translation from the laboratory bench to the bedside for testing in humans, translation from the patient beside at major academic health center research units to widespread medical practice, and translation from widespread practice into improvements in the public's health, healthcare, and health policies. In 2005, NIH announced an ambitious plan to create CTSAs at 60 universities, with the explicit goal of transforming the entire biomedical research enterprise to become more effectively translational in these ways, with the explicit goal of improved healthcare in this country. This has been a major undertaking and investment for NIH, but with the understanding that better treatments, better health, and growth in biotechnology industry will repay this many times over. The specific goals of NIH for the CTSA program are: 1) improving the way biomedical research is conducted across the country; 2) reducing the time it takes for laboratory discoveries to become treatments for patients; 3) engaging communities in clinical research efforts; and 4) training and developing the careers of the next generation of clinical and translational researchers.

Significant resources were promised to the research community in the form of major grants that provide the needed infrastructure, resources, education, and career development support to transform (see Zerhouni, E. Translational and Clinical Science —

Time for a New Vision. New England Journal of Medicine, 353:14, October 12, 2005), with the plan to roll-out 60 CTSAs nationally over five years. This started with the funding of 12 CTSAs programs in 2006, with enormous attention and great promise by the U.S. and international scientific communities. However, soon, with the years of near-level funding of NIH had drained the pool of resources that could be committed to supporting the growing CTSA network. Because of this, the NIH National Center for Research Resources (NCRR), that administers CTSAs, and the NIH Office of the Director, had to curtail support for CTSAs. By the time the funding of the second group of 12 CTSAs in 2007, and also for third group of 14, funded in 2008, the budgets that applying universities had constructed based on the original request for applications, which had been approved by the review process, were cut, in some cases by more than 50%. The proposals were peer-reviewed in an extremely competitive pool, and those funded were those deemed most meritorious based on their planned budgets. Nonetheless, the great promise of the CTSAs fell to the same axe that was causing funding difficulties throughout NIH.

Now, with the improvements in NIH funding brought by the stimulus package and the FY09 Appropriations, NCRR/NIH could potentially restart full funding of the current 38 CTSAs, but there remains concern about making such a commitment due to the long term commitment this would require for full funding of the goal of 60 fully-funded CTSAs. This deserves the attention and support of the Subcommittee.

In fact, the current situation is frustrating for current and prospective CTSA institutions. We applaud the funding for NIH, NCRR, and comparative effectiveness research (CER) that was provided through the economic stimulus package, and this would seemingly provide a start to repair the shortfall for CTSAs. However, presently, NCRR and other NIH Institutes and Centers are holding competitions and accepting proposals that will be reviewed in the coming months to allocate the stimulus funds. Many of the research activities which are being proposed are similar to activities the CTSAs already planned in their initial peer-reviewed applications, but have been unable to undertake due to a lack of funding. It makes more sense to us that this funding be allocated immediately to meritorious proposals made by CTSA recipients that have already been peer-reviewed and are therefore ready to be implemented right away. By doing so, NIH can fulfill the commitment to fully-supporting the CTSA program, and more immediately enable the impact of the economic stimulus legislation.

We fully understand that funding for the CTSA program over the long term will require sufficient appropriations on an annual basis. The CTSA program is currently funded at approximately $475 million. You will note from the attached professional judgment budget prepared by NCRR in December that to facilitate appropriate implementation the program should be funded at $573 million in FY 2010. Additionally, this document shows that to fully implement the program and support a network of 60 centers by 2011, a funding level of approximately $672 million is required.

It is our recommendation that the Subcommittee support full implementation of the CTSA program by providing $573 million in FY 2010 and $672 million of support in FY 2011, and by encouraging NIH to continue to build the program to 60 CTSAs.

2) The importance of continuing to support the K-Award research training and career development programs

As the CTSA program is rolled out, it is subsuming the activities of other NCRR programs, such as the K-30 Clinical Research Curriculum Awards (CRCA) that provides the curricular support for the development of badly needed graduate programs in clinical and translational research. However, while flat budgets slowed implementation of the CTSA network, the phasing out of K-30 awards continued on unimpeded. Last year the Subcommittee showed strong leadership and urged NCRR to continue the CRCA program for those institutions that had not yet received a CTSA. I am pleased to inform you that the NCRR has complied with this request, and recently the Center issued the K-30 re-competition notice. Thank you for taking an interest in clinical research training and please continue to do so moving forward!

These K-30 awards (and CTSAs, where these are in place) provide the curriculum to train the needed new generation of clinical and translational researchers, but they do not have funds to pay stipends or tuition for young physician-investigators to take these courses, nor does it supply the career development support for incorporating such an education into the first years of a researcher's career. Accordingly, these K-30 curriculum, are not leveraged as well as they could be; to do this, there must be new individual K-Awards to support young investigators to gain the needed skills for a successful career in modern clinical and translational research. Thus there is a great need to grow, not cut back, as has been done, K-23 Mentored Patient-Oriented Research Career Development Awards, K-01 Mentored Research Scientist Development Awards, K-08 Mentored Clinical Scientist Development Awards, among other K-Awards based at NIH and AHRQ. Similarly, for T-awards, analogous for selected young physician-investigators who are still in their training phase, also should be increased dramatically. All of these awards mechanism fill critical research training and career development niches, and these mechanisms need bolstered support. Related to this, it would leverage these awards to increase, not decrease as now is the case, K-24 Midcareer Investigator Awards in Patient-Oriented Research for faculty who can act as mentors to the junior faculty.

We ask the Subcommittee to emphasize its interest in the K-award programs and to urge NIH and AHRQ to continue to increase support for K-awards to develop the needed researchers for transforming biomedical research and improving its impact on health.

3) **The importance of continuing to support CER.**

The *American Recovery and Reinvestment Act of 2009* contained $1.1 billion for CER activities at NIH and the Agency for Healthcare Research and Quality (AHRQ). AHRQ has had a focus on CER especially since the Medicare Modernization Act, and NIH has been supporting critical CER for some time; we are pleased that Congress recognizes the importance of these activities and agree that CER's proper home is in a science agency in which the peer review processes and infrastructure are in place to ensure the highest quality science, rather than creating a new untested entity as a funding agency for this critical work.

Within the $1.1 billion allocation for CER, $400 million was provided to NIH. CTSA program recipients should compete well for a portion of these funds as many sites consider CER a crucial component of clinical and translational research. Additionally, the CTSA network is intended to be a collaborative endeavor capable of leveraging great resources to maximize productivity. As CER gains prominence, we hope the

Subcommittee will recognize the CTSA network as an ideal portal for comparative effectiveness research activities. The CTSAs can provide an infrastructure for CER that could immediately put to work the funding allocated to NIH via the stimulus package that would contribute to restoring the originally peer-reviewed and approved budgets.

We ask the Subcommittee to continue to appreciate and support CER activities at NIH and AHRQ.

Thank you for this opportunity to present the views and recommendations of the clinical research training community.

Appendix: Estimates of costs for fully funding CTSAs based on FY

NATIONAL INSTITUTES OF HEALTH
NATIONAL CENTER FOR RESEARCH RESOURCES (NCRR)

CTSA/GCRC Estimate Per Current Model
(Dollars in Millions)

Cohort	No.	FY 2009	FY 2010	FY 2011
FY 2006 Grants*	12	$140	$140	$116
FY 2007 Grants*	12	$120	$121	$121
FY 2008 Grants*	14	$107	$107	$107
FY 2009 Grants*	5	$36	$36	$36
FY 2010 Grants*	2		$14	$14
FY 2011 Grants*	15			$100
Total, CTSA Grants	60	$403	$418	$494
CTSA Support Contract		$3	$3	$3
K30 Recompetition			$5	$1
Total, CTSAs		$406	$426	$497
GCRCs		$69	$41	$3
Total, CTSAs/GCRCs		$475	$467	$500

CTSA/GCRC Estimate If Requested Amount Awarded
(Dollars in Millions)

Cohort	No.	FY 2009	FY 2010	FY 2011
FY 2006 Grants*	12	$140	$140	$140
FY 2007 Grants*	12	$158	$158	$158
FY 2008 Grants*	14	$155	$155	$155
FY 2009 Grants*	5	$50	$50	$50
FY 2010 Grants*	2		$21	$21
FY 2011 Grants*	15			$142
Total, CTSA Grants	60	$503	$524	$666
CTSA Support Contract		$3	$3	$3
K30 Recompetition			$5	$1
Total, CTSAs		$506	$532	$669
GCRCs		$69	$41	$3
Total, CTSAs/GCRCs		$575	$573	$672

- It would cost $666 million to fund 60 CTSAs at the amounts requested by the institutions, which is $166 million more than the $500 million budget.

Difference
(Dollars in Millions)

Cohort	No.	FY 2009	FY 2010	FY 2011
FY 2006 Grants*	12	$0	$0	$24
FY 2007 Grants*	12	$38	$37	$37
FY 2008 Grants*	14	$48	$48	$48
FY 2009 Grants*	5	$14	$14	$14
FY 2010 Grants*	2	$0	$7	$7
FY 2011 Grants*	15	$0	$0	$42
Total, CTSA Grants	60	$100	$106	$172
CTSA Support Contract		$0	$0	$0
K30 Recompetition		$0	$0	$0
Total, CTSAs		$100	$106	$172
GCRCs		$0	$0	$0
Total, CTSAs/GCRCs		$100	$106	$172

*UL1, KL2, and TL1 awards

- It would cost an additional $100 million in FY 2009, $106 million in FY 2010, and $172 million in FY 2011 to fund the CTSAs at the amounts requested by the institutions.