



December 3, 2010

Attn. Lyric Jorgensen  
Office of Science Policy  
Office of the Director  
National Institutes of Health  
6705 Rockledge Drive, Suite 750  
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Dear Members of the NIH Scientific Management Review Board:

The RCMI Program Directors' Association would first like to applaud the translational medicine and therapeutics working group for their thoughtfulness in advancing translational science at the highest level within the NIH. The RCMI Program Directors' Association also believes that translational medicine is an important approach for improving our nation's health. That being said, we have some genuine concerns related to the fast tracking of proposed changes that could inadvertently lead to the creation of an even greater silo having a disproportionately large focus and emphasis on therapeutics development and a comparatively limited focus and perspective on the traditional second and third phases of the translational research continuum, namely that of clinical research and clinical and community practice. Indeed, it was Dr. Claude Lenfant, the former director of the National Heart Lung Blood Institute, who elegantly articulated in his 2003 New England Journal of Medicine article, entitled "Clinical research to clinical practice: lost in translation?", that the enormous amounts of new knowledge barreling down the information highway are not arriving at the doorsteps of our patients. In that article, he rallied for the medical and research communities to direct their attention and commit their energies, creativity and resourcefulness to making sure that the beneficiaries of health science efforts will be the patients, all of the patients. In the spirit of Dr. Lenfant's insightful comments, the RCMI Program Directors' Association is concerned with what appears to be at this point a rather narrow interpretation of translational medicine with a major focus on preclinical issues without the translation to clinical practice.

The apparent paucity of translation from clinical research to patients and communities, and the apparent limited integration of key areas such as community engagement, practical trials, and practice-based research networks lead to concerns of the creation of yet a new silo and a potential backlash over a lack of commitment to the second phase of translational research. At present the NCRF has invested substantial resources into a more holistic vision of translational research through the Clinical and Translational Science Institutes and Centers, the RCMI Clinical and Translational Research Centers and many of the RCMI and IDeA program project centers that have evolved into thriving centers of translational science with robust basic, clinical, and community components. The NCRF support for the RCMI and IDeA programs, many of which work closely together and have led to substantial scientific advances relevant to the health of traditionally poor and underserved minority, urban and/or rural communities. Indeed,

the RCMI and IDeA programs epitomize the recommendations by Dr. Steven A. Schroeder in his 2007 New England Journal of Medicine Shattuck Lecture by focused on improving the health of American people, noting “that since all the actionable determinants of health — personal behavior, social factors, health care, and the environment — disproportionately affect the poor, strategies to improve national health rankings must focus on this population.” This reinforces the relevance of preserving the collaborations and partnerships between these two programs as well as the services that they provide to the communities they serve.

The RCMI Program Directors’ Association believes it will be crucial to include in this transition process a robust evaluation of the impact of a new institute on the clinical and translational science activities or elements within other NIH Centers and Institutes as well as other HHS health and science areas. There should also be a measured approach to leveraging the existing alliances both within the NCRR and between NCRR and other NIH Institutes and Centers. In addition, it is the belief of the RCMI Program Directors’ Association that education in the realm of translational research is optimized when trainees are exposed to the entire spectrum of translational science. Such an approach is most likely to positively influence the consciousness of the next generation of investigators in a way that allows them to capitalize on the content knowledge in their primary area of focus within a context of the multiple determinants of health that we believe is critical for them to bring the most value and relevance to their research to ensure scientific advances lead to health improvements for all Americans.

In summary, while we believe the direction of the translational medicine and therapeutics working group is positive, we believe the recommendations at this point in time need further refinement. We also strongly believe that following such refinement the recommendations are integrated into a robust evaluation plan to ensure that even a refined comprehensive/holistic Translational Research Institute is: 1) fully leveraging and building upon existing NCRR alliances and investments, 2) having a positive impact on translational programs within other NIH Institutes and Centers, and 3) is using an evidence-based approach to focus resources on those areas most likely to bring the maximum added value to the health outcomes of all patients, even those not aligned with more traditional NIH areas of emphasis.

Thank you for the opportunity to comment.

Sincerely



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