



Association for Patient-Oriented
Research

Clinical Research
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Internal Medicine



November 22, 2010

Scientific Management Review Board
ATTN: Lyric Jorgenson
Office of Science Policy, Office of the Director
National Institutes of Health
6705 Rockledge Drive, Suite 750
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Dear Scientific Management Review Board:

Together, the Association for Clinical Research Training (ACRT), the Association for Patient-Oriented Research (APOR), the Clinical Research Forum, the Society for General Internal Medicine (SGIM), the Society for Clinical and Translational Science (SCTS), and the Clinical and Translational Science Award (CTSA) principal investigators (PIs), represented by the Steering Committee co-chairs, are encouraged by much of the Scientific Management Review Board's (SMRB) proposed recommendations regarding the creation of a translational research institute at the National Institutes of Health (NIH). In response to the Board's November 10, 2010 request for public comment, we offer the following recommendations on behalf of the translational research communities we represent. Specifically, to maximize this opportunity, as the establishment of a translational research institute moves forward, we ask that **three critical topics be definitively addressed:**

First, the great advances made by the CTSA's and the CTSA Consortium in extending the reach of NIH sponsored translational research into the full spectrum of T1-T4 research should be sustained and advanced in the reorganization plan. In the diagrams on slides 27 and 28 of the Board presentation, this was not reflected: missing to the right of the depiction of clinical trials were comparative effectiveness research, community engaged research, dissemination science, and behavioral, policy, and other approaches to translate the results of biomedical research into maximal public benefit. Due to the complexity of translational research, researchers as well as physical infrastructure must fit appropriately into the full spectrum of translation, from basic discovery to actual implementation. In addition, the resources have to be sufficiently flexible to support more than drug development, including biomarkers, diagnostic tests, and behavioral interventions. We support NIH's explicit extension of the translational spectrum to include the science and methods of the translation of biomedical advances into practice and public impact that have been a key part of the CTSA program. We also support Dr. Collins' call for NIH to support reform of American health care, and thus we urge that you make explicit that this full spectrum of translation is a key part of the mandate of the new institute as part of its responsibility to the public.

Second, the structure of a new institute must take into consideration ongoing translational research currently being conducted across NIH through other ICs. We support your efforts to be

sure that the structure of a new institute be such that it will facilitate advancement of translational research being done at other ICs, as this will further support the long-term success of translational research led and supported by NIH.

Third, the opportunity for NIH-wide clinical and translational research training and career development programs should be leveraged in the creation of the new institute. There is a clear need for educating and supporting the next generation of diverse, well-educated clinical and translational research professionals, and we urge that you further leverage the strengths of the CTSA in advancing this crucial work. While there is a clear need for training and career development programs in the categorical ICs, as has been illustrated in the past by the K30 Program, and in recent years by the CTSA, the opportunity for rigorous methods research training cuts across diseases and organs, and it an appropriate focus for such a new institute.

As the world's foremost biomedical research entity, NIH has greatly advanced the translational research agenda through a number of crosscutting and institute-wide programs. In particular, the CTSA program administered through the National Center for Research Resources (NCRR) has created a unique academic home for clinical and translational research. The CTSA program has been particularly successful transforming their host institutions, and thus leveraging new resources and investments for research spanning the translational spectrum. As NIH seeks to expand the role of translational research throughout all 27 institutes and centers (ICs), we believe this program is uniquely suited to become a "superhighway" for the full spectrum of T1 through T4 translational research, bringing treatments and cures to the public and directly supporting the five goals Director Francis Collins put in place for the future of NIH.

We believe that the incorporation of the CTSA program into a translational research institute also including the Cures Acceleration Network (CAN), the Therapeutics for Rare and Neglected Diseases (TRND) program, the Molecular Libraries program, the Rapid Access to Interventional Development (RAID) program, and partnership with the Food and Drug Administration, in collaboration with the other ICs, will not only increase the speed with which new treatments could be brought to market, it will also take advantage of the leadership that CTSA have shown in moving early-stage translational research into public impact, by extending translational research into real-world use, comparative effectiveness research, and community engagement. Such an institute would serve as a concrete example of NIH's contributions to a more informed, more effective, and more efficient American healthcare system.

Thank you for the opportunity to share our thoughts on the future of translational medicine and therapeutics development at the NIH. We are encouraged by the SMRB's recommendations for the creation of this new institute, and believe that attention to the three issues we raise will help maximize this opportunity for our nation. We hope to assist you during any transition period, and to provide input as this process continues.

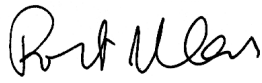
Sincerely,



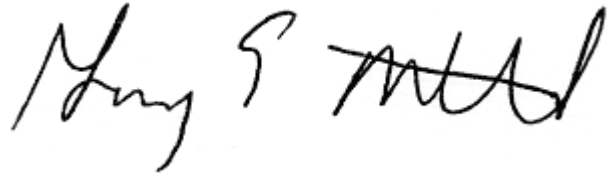
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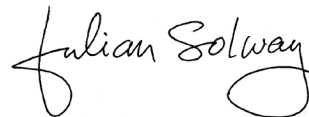
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