Statement

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Darrell G. Kirch, M.D.
President

on

The Draft Translational Medicine and Therapeutic Working Group Recommendations

Presented to the

Scientific Management Review Board
National Institutes of Health

By

David B. Moore
Senior Director
Government Relations
Association of American Medical Colleges

December 7, 2010

The Association of American Medical Colleges (AAMC) is grateful to the National Institutes of Health (NIH) and its Scientific Management Review Board (SMRB) for this opportunity to comment on the draft recommendations of the Translational Medicine and Therapeutic (TMAT) Working Group. The AAMC represents all 133 accredited U.S. medical schools, nearly 400 teaching hospitals and health systems, and 90 academic societies representing 128,000 faculty members. AAMC member institutions perform more than half of all extramural research supported by the NIH. Most all of the 55 active research institutions in the Clinical and Translational Science Awards (CTSA) consortia include AAMC member medical schools and teaching hospitals.

The AAMC would first like to thank the SMRB and its working groups for their dedication and diligence in conducting a thorough review of the NIH organizational structure with consummate sensitivity to the agency's public health mission and the quality of its science. The Association actively supported passage of the NIH Reform Act of 2006 that created the SMRB and other reforms to improve management for scientific and public health priorities. Even prior to that legislation, the AAMC had long endorsed reforms to permit NIH leadership more flexibility in managing and coordinating the agency's programs to meet emerging health needs and to address scientific opportunities.

The TMAT working group presented an excellent analysis of the NIH programs for support of clinical and translational medicine, and particularly the challenges of incorporating a new entity, the Cures Acceleration Network, within an effective structure for appropriate management and oversight. These challenges are made more acute—and the SMRB mission more critical—by the severe fiscal constraints currently confronting NIH, the research community, and the Nation. NIH and the medical research community share the imperative to ensure that NIH's organization most effectively focuses limited resources on critical scientific and health priorities.

The AAMC wishes to address two issues that we request the SMRB consider in its deliberations on the TMAT recommendations, in particular the establishment of a new organizational entity. The first regards the focus and objectives of the Clinical and Translational Science Awards program, which the working group recommends be moved to the new organization. The AAMC believes that this new entity should explicitly commit to advancing the CTSA's key objectives and emerging accomplishments. One of these objectives is the promotion of community outreach and community-based participatory research, not only to develop venues for clinical trials, but also to enlist communities as partners in identifying pathways and barriers for the translation of validated science into medical practice and public health. The CTSAs provide an historic opportunity for institutions and researchers to engage in long-term partnerships with communities and other organizations in health research. These partnerships involve time and resources, above all to build trust. To date, these partnerships have generated genuine enthusiasm among scientists and engaged communities, and the AAMC believes such collaborations will be among the consortia's early successes if they are allowed to develop.

Similarly, while the CTSAs are still relatively new, with just the first round of the initial five-year awards coming due for renewal this year, the consortia are succeeding in their objective to establish "homes" for clinical and translational research and for the training and career development of new clinical investigators, especially physician-scientists and scientists from

other health professions. The CTSA program was conceived on such an ambitious scale specifically to integrate clinical and translational research and research training across a broad spectrum of clinical and health science, and to support the translation of new knowledge into health practice. The CTSA institutions and their community partners have invested significant resources into this program (in addition to NIH funds) because these goals have been so compelling. While drug development should be one of the objectives of the new translational entity, it should not be the only focus. The new entity must foster the ability of the CTSA's and indeed the entire medical research enterprise to engage across the full continuum of translational research, including in areas especially relevant to the implementation of health care delivery reform. The AAMC urges that NIH's commitment to the CTSA's broad objectives be incorporated as a central theme underlying implementation of the new entity, and encourages the SMRB to affirm its commitment to the total spectrum of translational research as it considers the TMAT recommendations.

The AAMC's second concern is that the TMAT working group's proposals would profoundly affect other programs within the National Center for Research Resources (NCRR), and by extension the nation's medical schools and teaching hospitals. While other Institutes and Centers do support the development of infrastructure within their missions, NCRR is the only NIH organization dedicated to development of infrastructure and resources across all fields of medical and health research. The NCRR leadership and staff, and its council representing the communities that use, develop, and manage these resources, are dedicated to serving the broadest interests of the medical and health community (a mission somewhat comparable to the NIGMS mission for fundamental research). Further, the NCRR staff have developed the necessary expertise in assessing and supporting the resource needs of the extramural research community that must be preserved in any potential reorganization. For example, the Comparative Medicine Program, which provides for animal research resources, is indispensible to medical research and is no less fundamental than other NIH programs to translating laboratory discoveries into clinical or other applications.

The NCRR has led the way in establishing shared infrastructure and networks for collaboration that serve both the best interests of science and provide for more efficient use of limited resources. The AAMC believes that attention must be given to the impact of the TMAT recommendations on these valued resources, many of which are critically important to translational medicine and the overall NIH mission. The AAMC recommends that any deliberations on moving forward with the working group's recommendations also evaluate the best way to transfer NCRR's resource programs in a way that ensures their continued focus, integrity, and effectiveness.

On behalf of the AAMC's President, Darrell Kirch, its Board of Directors and member institutions, the Association is grateful to the SMRB and the NIH for this opportunity to comment, and I would be glad to answer questions about this statement or provide further information.

December 6, 2010

Mr. Norman Augustine
Chair, Scientific Management Review Board
Office of Science Policy
Office of the Director
National Institutes of Health
6705 Rockledge Drive, Suite 750
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Dear Chairman Augustine and Members of the NIH Scientific Management Review Board:

As the nation's sole representative for veterinary medical colleges, departments of comparative medicine, and departments of veterinary science, the Association of American Veterinary Medical Colleges (AAVMC) writes this letter to express its great interest in the deliberations of and upcoming recommendations from the Scientific Management Review Board (SMRB) with regard to measures by the National Institutes of Health (NIH) to advance translational medicine and therapeutics.

We fully recognize the importance of this new initiative and welcome the potential benefits a new institute with an invigorated focus on translational medicine and therapeutics will have on the nation's health. We applaud the emphasis that NIH has given to the importance of transdisciplinary involvement and collaboration in translational research, and investigators at our member institutions are proud to have made significant contributions to achieving the goals of translational research and comparative medicine in advancing best science toward improving human health. We greatly appreciate, therefore, the stated position of the SMRB not to disrupt extant programs that could and should aid in the advancement of this new initiative.

Pursuant to the latter, we believe it is critical that the value of the National Center for Research Resources (NCRR) and all of its multiple components to this initiative be fully recognized and not underestimated. The NCRR serves as a foundation for the entire NIH research enterprise. NCRR's matrix of extramural programs enable discovery across the entire continuum of research from basic science to community health care. More than 30,000 NIH-funded investigators nationwide rely on the resources, tools, and networks made possible through NCRR support.

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In particular, we wish to highlight the critical roles of the Divisions of Comparative Medicine, Research Infrastructure, and Biomedical Technology to advancing translational medicine. The programs and resources that depend on the success of these divisions, especially Comparative Medicine, are vital to discovering new knowledge and achieving substantive and significant new advances in translational medicine and therapeutics.

It is also imperative to point out that many of these programs and resources critical to the advancement of translational medicine and therapeutics are developed, conducted, and advanced within the nation's colleges of veterinary medicine, departments of comparative medicine, and departments of veterinary science, in addition to institutions of other health professions. Comparative medicine veterinary scientists at AAVMC institutions are uniquely positioned to understand and explore the interspecies comparisons that are an essential element of translational research. They are an indispensible component of the scientific workforce as both independent and collaborative investigators, with the knowledge and training required to add value to and avoid misinterpretation of experimental findings in animal model systems. The contributions of veterinary medical scientists in translational research and the need to sustain and expand this workforce are highlighted in two recent National Research Council publications: *National Need and Priorities for Veterinarians in Biomedical Research* (National Academy Press, 2004) and *Critical Needs for Research in Veterinary Science* (National Academy Press, 2005).

We applaud the NIH for prioritizing translational research in its assessment and evaluation of NIH resources and the recognition of the high value of NCRR programs in advancing progress in translational medicine and therapeutics. We are aware of the proposal by the Translational Medicine and Therapeutics (TMAT) Working Group to the SMRB, to create a new NIH categorical institute of Translational Medicine and Therapeutics, which includes a recommendation to move the Clinical and Translational Science Award (CTSA) program from the NCRR and to this new institute. From the public information available on the TMAT recommendations, we recognize that the SMRB and TMAT may benefit from a better understanding of the role and functions of critical programs and the necessity to maintain and enhance them as NIH seeks to determine the optimal redistribution and reorganization of NCRR programs. A few examples of essential programs include NCRR grants to academic veterinary medical institutions to train veterinarians to meet national biomedical research needs, to construct and renovate research facilities, and to create and maintain research resource centers that are utilized by grantees from all of NIH’s categorical institutes.

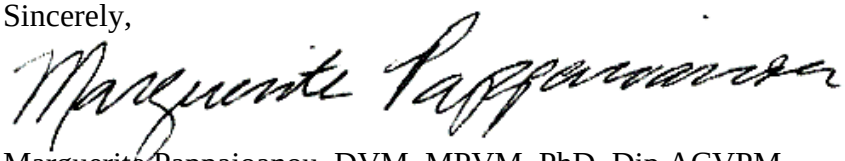
We, the AAVMC member institutions, therefore recommend that the SMRB:

1. **Take additional time to consider the foregoing so as to make a more comprehensive recommendation to the NIH leadership.**

2. **Develop a stakeholders' group to advise the NIH leadership on the reorganization plan for the future of NCRR programs. The advisory group should include representatives of the colleges of veterinary medicine, departments of the comparative medicine, and departments of veterinary science.**

The AAVMC would be pleased to assist in recommending individuals for an advisory group. Please do not hesitate to contact me at (202) 371-9195, ext 115, or mpappa@aavmc.org.

Sincerely,



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November 24, 2010

Mr. Norman Augustine, Chair
Scientific Management Review Board, OD, NIH
Building 1, Room 103
9000 Rockville Pike
Bethesda, MD 20892
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Dear Mr. Augustine:

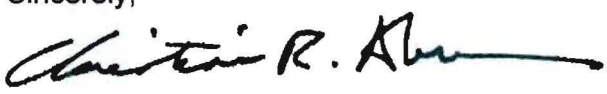
In the November 2010 meeting of the Scientific Management and Review Board (SMRB), a report was presented by the Translational Medicine and Therapeutics (TMAT) Working Group to create a new National Institutes of Health (NIH) categorical institute of Translational Medicine and Therapeutics. This plan included a recommendation to take current programs supported within the National Center for Research Resources (NCRR) and move them into this new institute. While there may be considerable merit in organizing multiple translational medicine programs supported by NIH into one institute dedicated to translation medicine, this recommendation carries very serious issues and implications that could threaten the national biomedical research infrastructure.

The NCRR was established to provide a means for NIH to create and maintain national research resources intended to meet the needs of NIH intramural research programs and extramural grantees of multiple categorical institutes. Thus, NCRR's programs within the divisions of Clinical Research Resources, Comparative Medicine, Biomedical Technology, and Research Infrastructure provide most of the federal support for creating and maintaining our nation's research infrastructure. A few examples include grants from these divisions that have provided the funding to train veterinarians to meet national biomedical research needs, to construct and renovate research facilities in research institutions across the country, and to create and maintain research resource centers that are utilized by grantees from all of NIH's categorical institutes.

The recommendation of the TMAT Working Group addresses only the Division of Clinical Research Resources while all of the other programs contributing to biomedical research infrastructure remain in doubt and possibly in jeopardy. Of additional concern is the possibility that these programs will be re-organized into other categorical institutes on a "best fit" basis. The missions of these institutes do not include creation of research resources that meet needs outside that respective institute. Therefore, if each institute is forced to create its own mission relevant resources, the efficiencies created by the multi-categorical nature of NCRR's programs will be lost.

The concept of organizing all Translational Medicine resources within one institute is very attractive. However, this recommendation should not come at the expense of the national biomedical research infrastructure or the multi-categorical mission of the resources currently supported by the NCRR. For these reasons, we urge the SMRB carefully reconsider this recommendation to make certain that our nation's research infrastructure is not compromised.

Sincerely,



Christian R. Abee, D.V.M., M.S., DACLAM
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Copies: Dr. Francis Collins (francis.collins@mail.nih.gov)
Dr. Authur Rubenstein (smrb@mail.nih.gov)

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Dr. Arthur Rubenstein, M.B.B.Ch.
Chair, NIH Scientific Management Review Board (SMRB)

Dr. Frances Collins, M.D., Ph.D.
Director, National Institute of Health

December 7, 2010

Dear Dr. Rubenstein and Dr. Collins:

The Association of Biomolecular Resource Facilities (ABRF) comprises over 700 scientists dedicated to advancing core facilities and research biotechnology laboratories, including genomics, proteomics and other 'omic' technologies that underlie biomarker discovery and translational medicine. We actively pursue the benchmarking of research methods, equipment and reagents, provide membership education, facilitate technology adaptation, and promote good core facility management practices. Throughout the 22 year history of our society, the NCRR has been there to provide our members and the researchers they serve with significant support. The NCRR has established coherent national efforts geared towards improving the efficiency of core and shared resource facilities, maximizing the best use of federal dollars for the purchase and operation of high end and costly core instrumentation, and has recently provided leadership in the efforts to create a national registry of core facilities and research scientists. This registry will promote the sharing of core equipment and expertise at regional and national levels. These initiatives of NCRR are, in our opinion, original and key to the competitiveness of the research enterprise in this nation and are beginning to bear fruit at a high level.

With regard to the planned creation of the National Center for Translational Medicine and Therapeutics we are concerned about the potential dissolution of the NCRR that might ensue in its wake. Importantly, NCRR programs provide key infrastructure and support for core facilities and their personnel, including the Shared Instrumentation Grants, funds for facility renovation and improvement, leadership in the efforts of core consolidation, programs to support the education of core management, and the support of the Network of IDeA-funded Core Laboratories (NICL). We strongly feel that our nation must maintain these services, currently provided by the NCRR, that have enabled core facilities and their collaborative research base to remain on the leading edge of science and discovery. Therefore we hope these critical aspects of the NCRR mission will be preserved in whatever new organizational structure that might emerge for the NIH.

Thank you very much for your attention and leadership in this important matter.

Yours truly,

The Executive Board of the ABRF

American College of Laboratory Animal Medicine

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December 4, 2010

Mr. Norman Augustine, Chair
Scientific Management Review Board, OD, NIH
Building 1, Room 103
9000 Rockville Pike
Bethesda, MD 20892
smrb@mail.nih.gov

Dear Mr. Augustine:

I write to you representing 964 veterinary specialists of the American College of Laboratory Animal Medicine (ACLAM). As members of the biomedical research community with a primary mission to support comparative and translation research conducted in animal models, we would like to comment on the November 2010 report by the Translational Medicine and Therapeutics (TMAT) Working group to create a new NIH institute of Translation Medicine and Therapeutics.

While the formation of this Institute or Center is an opportunity to advance translational and therapeutic medicine, there are some critical points that should be highly considered in order to avoid potential risks to our nation's biomedical research infrastructure.

The Division of Comparative Medicine within the National Center for Research Resources (NCRR) has been key to advancing the United States' biomedical research mission. Support from this division has not only helped train critically needed professionals, such as veterinarians and veterinary scientists, to meet the demands of translation research, but also allowed support for key biomedical resources such as the Knockout Mouse Project, the Mutant Mouse Resource Centers, the Drosophila Stock Center, the Zebrafish Resource Center and the eight National Primate Research Centers. This support has provided key resources, efficiently and cost effectively, to facilitate our nation's biomedical research.

We appeal to the Scientific Management Review Board give strong consideration to and seek expert input from the many comparative medicine veterinary scientists and specialists to maintain the important mission of NCRR's Division of Comparative Medicine either independently, as it currently is placed within NCRR, or through intact transfer to the proposed Center for Translational Medicine and Therapeutics. Please let me know how our College can be of further assistance in future discussions on this subject.

Sincerely,

Ravi Tolwani

Ravi Tolwani, D.V.M., Ph.D.
President, American College of Laboratory Animal Medicine

Copies: Dr. Francis Collins (francis.collins@mail.nih.gov)
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AMERICAN PEDIATRIC SOCIETY

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November 29, 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
Bethesda, MD 20892

Dear Scientific Management Review Board:

The American Pediatric Society (APS) represents the leaders in academic pediatrics in the US. The APS is committed to promoting child health in our country through research and medical care of children, noting specifically that improved health of children provides lifelong benefits, personally, socially, and economically. We specifically believe that advances in biomedical and behavioral science that benefit child health outcomes must be translated into practice, quickly and efficiently; that children should receive the most advanced medical care so they can lead healthy and productive lives; and that advancing pediatric research improves both pediatric and adult health.

We 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 leaders of academic pediatrics and on behalf of children in the US. Specifically, to maximize this opportunity of creating a new NIH Institute for Translational Medicine and Therapeutic, we ask that **this new institute specifically address:**

(1) The great advances made by The Eunice Kennedy Shriver National Institute of Child Health and Human Development and the Child Health Oversight Committee in the CTSA Consortium in extending the reach of NIH-sponsored translational research into the full spectrum of child health T1-T4 research; these efforts should be sustained and advanced in the reorganization plan. Missing in the many slides of the Board presentation was the specific inclusion of support for all aspects of child health research and other approaches to translate the results of biomedical and behavioral research in children into maximal benefit, for children and for the public in general. Translational research agendas have often neglected a specific focus on and support for child health translational research, limiting support for child health researchers as well as physical infrastructure for child health research that must fit appropriately into the full spectrum of translation, from basic discovery to actual implementation. 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. We also urge that you make an explicit commitment in the new TMAT Institute that the full spectrum of translational research will include specific support for child health translational research as a key part of the mandate of the new institute and as part of its responsibility to children and to the general public.

(2) The structure of a new institute must take into consideration ongoing translational research in all areas of child health currently being conducted by NICHD and other institutes with a pediatric research portfolio. We also support your efforts to ensure that the structure of a new institute will facilitate advancement of translational research specifically including child health research being done at other ICs, as this will further support the long-term success of child health translational research led and supported by NIH.

(3) The opportunity for NIH-wide clinical and translational research training and career development programs in a new TMAT Institute should include specific support for those who aim for careers in child health and diseases unique to childhood. 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 new TMAT Institute to advancing this crucial work for children. While there is a clear need for training and career development programs in all of the categorical ICs, the opportunity for rigorous research methods training must include specific support for training of translational researchers in child health, noting specifically that improved health of children provides lifelong benefits, and that advancing pediatric research improves both pediatric and adult health.

(4) Since the CTSA program may well be moved to the new TMAT Institute, the APS considers it fundamental that the new TMAT Institute support the functions of the CTSA Consortium Child Health Oversight Committee and emphasize NIH's commitment to continue to ensure that CTSA infrastructure and programs are equitably available to child health researchers and trainees. We strongly endorse the statements by 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, in their letter of November 22, 2010 to you—*"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."* The APS strongly adds to these statements the need to establish a specific and material commitment in this new TMAT Institute to support child health research and training of future child health researchers using current and future organizational structures, funds, and other opportunities to ensure that infrastructure and programs of the new TMAT Institute are equitably available to child health researchers and trainees.

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 four issues noted above on behalf of child health research, child health researchers, and children and the general public at large will help maximize this opportunity for our children and our nation. We hope to assist you during any transition period, and to provide input as this process continues.

Sincerely,

Gary R. Fleisher, M.D.
President, American Pediatric Society

Judy Aschner, M.D.

Judy L. Aschner, M.D.
Secretary-Treasurer, American Pediatric Society

William W. Hay, Jr., M.D.
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December 3, 2010

Mr. Norman Augustine
Head, Scientific Management Review Board (SMRB)

Dear Mr. Augustine:

As representatives of the American Society for Mass Spectrometry, we would like to express our concerns about possible significant organizational changes at the NIH that may take place relatively quickly and without much stakeholder input. Specifically, information has been circulating that the National Center for Research Resources will be dissolved in conjunction with creation of a new Center that will house the NCRR Clinical Translational Science Awards (CTSAs). We have no concerns with the creation of the new center. However, there are many important programs, currently managed through NCRR, for which no information has been forthcoming regarding plans for their disposition within the new organizational structure. These include, for example, the shared instrumentation programs, which support the efforts of many biomedical investigators nation-wide, as do the many Biomedical Technology Resource Centers. Neither has there been an opportunity for stakeholders to consider proposed organizational realignments and provide input. We therefore urge the Scientific Management Review Board to adopt a more deliberate process that provides sufficient time to determine the potential consequences of the proposed rearrangement on the extremely valuable NCRR programs that will not be included in the new Center. In its current independent structure, synergy among programs is a hallmark of the NCRR, substantially enhancing the positive impact of the NCRR on the biomedical research community as a whole. It is essential that careful consideration be given to the design and implementation of such a major reorganization and that planning for such far-reaching changes be made with sufficient transparency and external input to engender confidence that the best overall solutions have been achieved.

Sincerely,

Scott A. McLuckey
President, ASMS

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December 6, 2010

Scientific Management Review Board
ATTN: MS. LYRIC JORGENSON
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Office of the Director, National Institutes of Health
6705 Rockledge Dr, Suite 750
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smrb@mail.nih.gov

VIA E-MAIL ONLY

Dear Chairman Augustine and Members of the NIH Scientific Management Review Board:

I am writing on behalf of the American Veterinary Medical Association (AVMA), established in 1863 and the largest veterinary medical association in the world. As a not-for-profit association established to advance the science and art of veterinary medicine, the AVMA is the recognized national voice for the veterinary profession. The Association's more than 81,000 members comprise approximately 83% of US veterinarians, all of whom are involved in myriad areas of the profession, including biomedical and comparative medical research; private and corporate practice; and academic, industrial, governmental, military, and public health services.

The AVMA thanks the Scientific Management Review Board (SMRB) for this opportunity to provide comments on the recommendations from the Translational Medicine and Therapeutics (TMAT) working group, which will be considered for potential decision by the SMRB at its December 7, 2010 meeting. It is our understanding that these recommendations call for a strengthening of existing federal translational and comparative medicine programs into a new institute/center (IC) with strong functional ties to the NIH Clinical Center. Key components of the proposed new IC are the recently authorized Cures Acceleration Network (CAN) and the established Clinical and Translational Science Awards (CTSA) program and consortium, which is currently an integral component of the NIH's National Center for Research Resources (NCRR).

The AVMA wishes to emphasize that the NCRR comprises not only the CTSA consortium, but also multiple other important programs, including those administered through its four divisions—Comparative Medicine, Clinical Research Resources, Biomedical Technology, and Research Infrastructure. It is of concern to the AVMA that the TMAT recommendations, which were summarized in a presentation given on November 10, 2010, made no reference to these other important NIH/NCRR programs. It is the AVMA's belief that the strength of the NCRR lies in the synergy within the programs administered through each of its divisions. Taken as a unit, each division contributes to the foundation of the entire NIH research enterprise. Thus, regardless of the final organizational structure selected to strengthen translational and therapeutic development research, the AVMA believes the SMRB should maintain the integrity of each of the NCRR's divisions and programs to continue the NCRR's critical role within the NIH.

Of particular importance to the AVMA and its more than 81,000 members are the programs administered through the NCRR's Division of Comparative Medicine (DCM). The AVMA defines comparative medicine as a discipline in which the similarities and differences in biology among animals enhance the understanding of mechanisms of human and animal disease alike. In this way, biomedical research, clinical studies, and ultimately, therapy directed at experimentally induced and spontaneously occurring diseases in animals form the basis for animal models of human and animal disease. In other words, comparative medicine embodies translational

medicine. Further, because veterinary medical education is firmly based on a comparative and one-medicine approach, veterinary scientists are uniquely positioned to play an essential role in translational research. The study of spontaneously occurring disease in domestic animals and wildlife and disease pathogenesis in laboratory animals play an essential role in biomedical and therapeutic development research. Veterinary scientists have a critical role not only in drug discovery, but also in the safety assessment of drugs and devices. Development of new drugs and medical therapies will not be effective without the help of animal research. In addition, we now recognize that over two-thirds of new emerging infectious diseases of humans arise in animals. In summary, veterinary scientists understand the health and welfare needs of all species of laboratory animals and are able to ensure those needs are met; the usefulness and limitations of animal models; and the regulatory requirements to bring a new human drug to market—all key components of translational medicine and therapeutic development research. As such, the AVMA strongly supports and affirms the recognition by the NIH of the role of veterinarians as scientists, educators, trainers, and collaborating partners in scientific research that takes a comparative, one-medicine approach to improvements in human and public health, as stated in the NCRR 2009-2013 strategic plan (www.ncrr.nih.gov/strategic_plan/).

Current DCM programs provide individual researchers and research institutes both within and outside the NIH with laboratory animal resources ranging from aquatic and rodent species to nonhuman primates; invertebrate and vertebrate comparative models for translating basic biomedical research results into clinically useful therapeutics; and career development opportunities for predoctoral veterinary students and individuals with DVM or PhD degrees to ensure a continued pipeline of scientists experienced in comparative medicine. To the AVMA, each of these DCM programs is as essential a component of a strong translational medicine and therapeutic development research institute as are the CAN and CTSA programs. The AVMA urges the SMRB to recognize the ongoing and urgent need for career development of researchers focused on comparative medicine, as has been previously recommended by two National Research Council committees (*Critical Needs for Research in Veterinary Science*, published in 2005; and *National Need and Priorities for Veterinarians in Biomedical Research*, published in 2004). The successful individual and institutional training grants and independent scientist award programs administered through the NCRR are vital to ensure the continuation and growth of the current pipeline leading to future comparative and translational medical research scientists.

In summary, then, the AVMA respectfully recommends that the SMRB:

1. maintain the integrity of each of the NCRR's divisions regardless of the final action taken on the recommendations of the TMAT to ensure that the current divisional programs retain synergistic strength.
2. maintain the Division of Comparative Medicine as an intact unit within the new translational medicine IC proposed by the TMAT should that structure be approved or within an existing but broad-based IC.

We thank you for the opportunity to provide input to the SMRB. Should you have questions, please feel free to contact Dr. Elizabeth Sabin (esabin@avma.org; ext 6675) in the AVMA's Education and Research Division.

Yours sincerely,

A

FOR: W. Ron DeHaven, DVM, MBA
Executive Vice President, CEO

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December 6, 2010

Scientific Management Review Board
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VIA E-MAIL ONLY

Dear Chairman Augustine and Members of the NIH Scientific Management Review Board:

I am writing on behalf of the American Veterinary Medical Association (AVMA), established in 1863 and the largest veterinary medical association in the world. As a not-for-profit association established to advance the science and art of veterinary medicine, the AVMA is the recognized national voice for the veterinary profession. The Association's more than 81,000 members comprise approximately 83% of US veterinarians, all of whom are involved in myriad areas of the profession, including biomedical and comparative medical research; private and corporate practice; and academic, industrial, governmental, military, and public health services.

The AVMA thanks the Scientific Management Review Board (SMRB) for this opportunity to provide comments on the recommendations from the Translational Medicine and Therapeutics (TMAT) working group, which will be considered for potential decision by the SMRB at its December 7, 2010 meeting. It is our understanding that these recommendations call for a strengthening of existing federal translational and comparative medicine programs into a new institute/center (IC) with strong functional ties to the NIH Clinical Center. Key components of the proposed new IC are the recently authorized Cures Acceleration Network (CAN) and the established Clinical and Translational Science Awards (CTSA) program and consortium, which is currently an integral component of the NIH's National Center for Research Resources (NCRR).

The AVMA wishes to emphasize that the NCRR comprises not only the CTSA consortium, but also multiple other important programs, including those administered through its four divisions—Comparative Medicine, Clinical Research Resources, Biomedical Technology, and Research Infrastructure. It is of concern to the AVMA that the TMAT recommendations, which were summarized in a presentation given on November 10, 2010, made no reference to these other important NIH/NCRR programs. It is the AVMA's belief that the strength of the NCRR lies in the synergy within the programs administered through each of its divisions. Taken as a unit, each division contributes to the foundation of the entire NIH research enterprise. Thus, regardless of the final organizational structure selected to strengthen translational and therapeutic development research, the AVMA believes the SMRB should maintain the integrity of each of the NCRR's divisions and programs to continue the NCRR's critical role within the NIH.

Of particular importance to the AVMA and its more than 81,000 members are the programs administered through the NCRR's Division of Comparative Medicine (DCM). The AVMA defines comparative medicine as a discipline in which the similarities and differences in biology among animals enhance the understanding of mechanisms of human and animal disease alike. In this way, biomedical research, clinical studies, and ultimately, therapy directed at experimentally induced and spontaneously occurring diseases in animals form the basis for animal models of human and animal disease. In other words, comparative medicine embodies translational

medicine. Further, because veterinary medical education is firmly based on a comparative and one-medicine approach, veterinary scientists are uniquely positioned to play an essential role in translational research. The study of spontaneously occurring disease in domestic animals and wildlife and disease pathogenesis in laboratory animals play an essential role in biomedical and therapeutic development research. Veterinary scientists have a critical role not only in drug discovery, but also in the safety assessment of drugs and devices. Development of new drugs and medical therapies will not be effective without the help of animal research. In addition, we now recognize that over two-thirds of new emerging infectious diseases of humans arise in animals. In summary, veterinary scientists understand the health and welfare needs of all species of laboratory animals and are able to ensure those needs are met; the usefulness and limitations of animal models; and the regulatory requirements to bring a new human drug to market—all key components of translational medicine and therapeutic development research. As such, the AVMA strongly supports and affirms the recognition by the NIH of the role of veterinarians as scientists, educators, trainers, and collaborating partners in scientific research that takes a comparative, one-medicine approach to improvements in human and public health, as stated in the NCRR 2009-2013 strategic plan (www.ncrr.nih.gov/strategic_plan/).

Current DCM programs provide individual researchers and research institutes both within and outside the NIH with laboratory animal resources ranging from aquatic and rodent species to nonhuman primates; invertebrate and vertebrate comparative models for translating basic biomedical research results into clinically useful therapeutics; and career development opportunities for predoctoral veterinary students and individuals with DVM or PhD degrees to ensure a continued pipeline of scientists experienced in comparative medicine. To the AVMA, each of these DCM programs is as essential a component of a strong translational medicine and therapeutic development research institute as are the CAN and CTSA programs. The AVMA urges the SMRB to recognize the ongoing and urgent need for career development of researchers focused on comparative medicine, as has been previously recommended by two National Research Council committees (*Critical Needs for Research in Veterinary Science*, published in 2005; and *National Need and Priorities for Veterinarians in Biomedical Research*, published in 2004). The successful individual and institutional training grants and independent scientist award programs administered through the NCRR are vital to ensure the continuation and growth of the current pipeline leading to future comparative and translational medical research scientists.

In summary, then, the AVMA respectfully recommends that the SMRB:

1. maintain the integrity of each of the NCRR's divisions regardless of the final action taken on the recommendations of the TMAT to ensure that the current divisional programs retain synergistic strength.
2. maintain the Division of Comparative Medicine as an intact unit within the new translational medicine IC proposed by the TMAT should that structure be approved or within an existing but broad-based IC.

We thank you for the opportunity to provide input to the SMRB. Should you have questions, please feel free to contact Dr. Elizabeth Sabin (esabin@avma.org; ext 6675) in the AVMA's Education and Research Division.

Yours sincerely,

A

FOR: W. Ron DeHaven, DVM, MBA
Executive Vice President, CEO

The UNIVERSITY of VERMONT

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December 2, 2010

Scientific Management Review Board
NIH

Dear Review Board Members:

I am writing as a PI for one of the COBRE programs at The University of Vermont and wish to convey in the strongest possible terms my delight in the success of this and the IDeA program in general. By almost any metric IDeA has been a success story. In addition, I have found the NCRR staff with whom I have interacted to be among the most professional, well informed, and helpful of any NIH staff with whom I have interacted during my 20 years of NIH funding. It is an NIH jewel in my opinion and should not be tampered with.

During the past five years of our Phase I COBRE program, we were able to recruit and support 9 new faculty. They alone have already brought in more than $8 million in funding, whereas the faculty as a whole garnered $48 million during the same five-year period, not counting any COBRE funds! Our publication record is equally impressive. That is a huge leveraged return on the $10.5 million COBRE funding, and unprecedented on this campus, except within our two other COBRE programs.

Beyond the recruitment of new faculty, the COBRE program has supported our seminar series, core facilities, and students. It allowed me to bring together for the first time on this campus the disciplines of immunology and infectious diseases. This would absolutely not have been possible without the COBRE support, as we are a small research university with minimal state support and very little endowment.

Recognizing the regional benefits of having such programs and intellectual capital distributed throughout the country is a concept that I fully embrace and one at which NCRR staff have been particularly adept. I strongly urge you to maintain the IDeA, RCMI and CTSA programs within NCRR. They know how to do it.

Sincerely yours,

Ralph C. Budd, M.D
Director, Vermont Center for Immunology and Infectious Diseases

From: Concannon, Thomas W [mailto:tconcannon@tuftsmedicalcenter.org]
Sent: Tuesday, November 23, 2010 5:06 PM
To: SMRB (NIH\OD)
Subject: TMAT Working Group Recommendations

NIH Scientific Management Review Board:

I have read with interest the Scientific Management Review Board's *Report on Deliberating Organizational Change and Effectiveness* and the Translational Medicine and Therapeutics Working Group's *November 10 presentation* recommending a new IC for translational medicine and therapeutics with strong functional ties to Clinical Centers. I am writing to offer my comments on the proposal.

In general, I believe this is the right approach to meet emerging demands for improved and speedier translation of basic science discoveries to application in clinical medicine. I believe that the establishment of a new IC within NIH to meet these demands is critical.

However, the recommendations are focused solely on early stage translation of basic science discoveries into clinical applications, without any discernable attention to translation into effective health care practice. As we know from clinical and health services research, the appearance of new clinical interventions in the health care marketplace does not guarantee appropriate translation into the practice of medicine. Research into improvements in the translation of clinical interventions into clinical practice has substantial promise for improving the nation's health, and this latter stage translational activity should be a key part of any effort to improve translational research at NIH.

I believe that the TMAT working group recommendations need substantially more attention to latter stage translational activities. Specifically, I recommend that TMAT revisit the decision to locate functional responsibilities for translation solely in the Clinical Center. This functional responsibility should be shared with CTSAs (option 2 on slide 27 in the November 10 presentation). The CTSAs have demonstrated expertise on latter stage translation activities, as evidenced by their active engagement in comparative effectiveness research (CER), and the establishment of the CTSA CER Forum on NIH's main campus on December 1, 2010 (next week). In order to assure that research into new pipeline drugs is conducted with the health care marketplace in mind, CTSAs should play an active role in IC for translational medicine.

Thank you for the opportunity to comment on the proposal.

Sincerely,

Thomas Concannon

--

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Dr. Lyric Jorgensen
Office of Science Policy
Office of the Director
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

December 1, 2010

Dear Dr. Jorgensen,

Statement by Comparative Medicine Institutional Training Grant Directors to the National Institutes of Health Scientific Management Review Board

The directors of the 45 veterinary institutional training grants supported by the National Center for Research Resources (NCRR) submit the following comments to the Translational Medicine and Therapeutics (TMAT) working group and the NIH Scientific Management Review Board (SMRB).

We would like to emphasize the value of the NCRR, and in particular the institutional training grants currently administered by the Division of Comparative Medicine (DCM), to the success of biomedical research and translational medicine. These grants address an important infrastructure need for biomedical research by providing high-quality, mentored training in comparative medical research for veterinarians. Regardless of the organizational fate of the NCRR, the "training pipeline" it provides is a critical element of our national research infrastructure and should not be lost or diverted.

Comparative medical veterinary scientists are uniquely positioned to understand and explore the interspecies comparisons that are an essential element of translational research. They are an indispensible component of the scientific workforce as both independent and collaborative investigators, with the knowledge and training required to avoid misinterpretation of experimental findings in animal model systems. The need for such qualified individuals is outlined in the National Research Council's publication *National Need and Priorities for Veterinarians in Biomedical Research* (National Academy Press, 2004).

The vital contribution of comparative medical veterinary researchers to the development of therapeutic agents is most evident in those studies requiring use of the Food and Drug Administration's Animal Rule, which governs the development of new drug and biological drug products when human efficacy studies are not ethical or feasible. The rule requires (1) "a well-understood pathophysiological mechanism", (2) "a sufficiently well-characterized animal model", (3) a study endpoint "clearly related to the desired benefit in humans", (4) "[understanding of] pharmacokinetics and pharmacodynamics [sufficient to expect] effectiveness in humans" (FDA, Federal Register 2002, 67:37988-98). Any meaningful degree of validity in the assessment of these criteria requires the expertise of veterinarians trained in research.

We believe that the training provided for comparative medical veterinary scientists should be supported by a non-categorical mechanism, because the nature of the skills provided by our training programs exceeds the purview of any specific categorical NIH institute. While some graduates of our programs have gone on to specialize in a field supported by a specific institute, most work collaboratively across multiple organ systems or disease entities.

The Division of Comparative Medicine has served translational medicine well to date, and is poised to flourish in the context of the new Center for Translational Science proposed by the TMAT working group. The program directors and administrators have the extensive experience and insight necessary to bring the capabilities of veterinary and comparative scientists to bear in the service of human health needs.

We therefore recommend:
1. That individuals with appropriate comparative medical expertise be involved in the development of the reorganization plan for the future of NCRR programs

and

2. That the Division of Comparative Medicine and the programs it oversees be maintained as is or become fully incorporated as an entire unit in future configurations of the NIH.

Representative for the Training Directors:

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The following Directors of DCM T32 and T35 Institutional Training Grants have reviewed and approved this statement:

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Dear Mr. Augustine: October 15, 2010

Our virtual paths have crossed again. In the fall of 1991 I joined GE Aerospace and was in a holding tank for 7 months awaiting clearance. During that time the merger was announced and I led a small group that studied the merger and gave presentations on it. (Much more fun than sitting around talking to each other all day with nothing to do.) My portion of the presentation was to find out about you. I read Augustine's Laws for example and found you to be a person of great integrity that we could all be comfortable working under.

I am now retired and have founded a non-profit public charity, the Foundation for Alcoholism Research (FAR). www.alcoholismresearch.org. Recently I received an email from a researcher and member of the Research Society on Alcoholism and she told me about the potential new institute at NIH and asked whether our organization wanted to write letters about this etc.

To this end I spent the better part of 2 days this week watching the video on my computer (all of Day 1 and the second part of Day 2) of the SMRB. How delighted I was to see you as the chair. Throughout the proceedings I was struck by the cordiality of all the participants toward each other and I credit that to you.

I was also discouraged from trying to rally FAR and other organizations that I am in contact with to persuade Dr. Collins to go against the recommendation of the Board.

However, I would like to list a few comments/observations on the meeting, which I am also sending to Dr. Collins:

1. It was useful for me to hear about resources available to researchers should FAR ever get in a position to be able to use them.
2. I was increasingly discouraged to hear that all the conversation centered on the production of drugs until minute 386 on Day 1 when Dr. Varmus noted that - and cited other health approaches. At FAR we would like to see a test for example to determine whether someone is predisposed to alcoholism – not based on behavioral background but scientific – such as brain structure or function, metabolism, genetics…. Then we would like to know what preventive measures may be taken (diet, targeted intervention?). It is folly to think that people can change life circumstances.
3. Dr. Duncan, as well as others, referred to neglected diseases. I feel that alcoholism is a neglected disease. The NIH AIDS budget (~4 million) is about 10 times larger than the NIH NIAAA budget (~400,000) and yet there are 1.1 million people in the US with AIDS and 17.6 million with alcoholism. (See attached chart). CDC does not include alcoholism at all. Yet CDC does address other non-infectious diseases.
4. It was especially encouraging to hear about Translational Medicine and bringing multiple disciplines together. You made an excellent point about older scientists who are confident and ready to look at the larger picture taking on that role of solving larger problems – as do systems engineers. However, that concept of a multidisciplinary approach did not enter into the addiction institute discussion. I

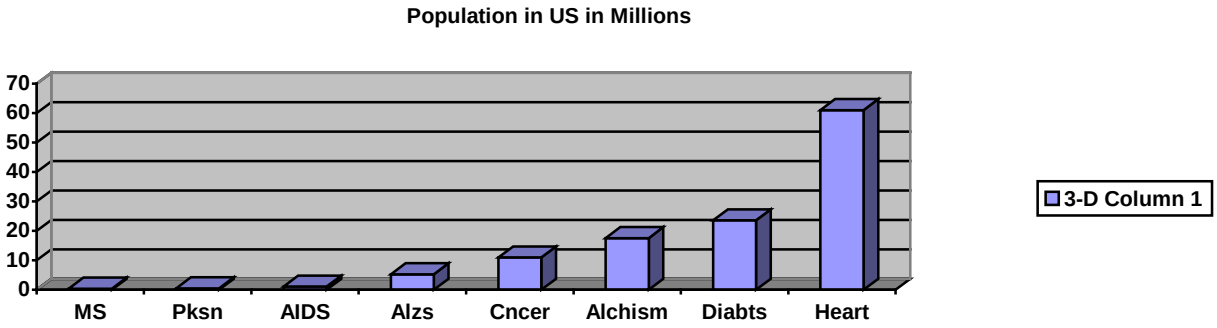
did not note the name of the Dr. who is heading the TMAT effort and who was in German industry but IMHO – HIS organization is where the alcoholism research belongs. And I do stress alcoholism, the disease (vs alcohol or alcohol consumption).

5. The discussion about a manager for taking a concept from basic research to product is exactly the role of the Product Manager in a computer company. That may be a model to look at for that purpose.
6. Dr. Gail Cassell (?) made remarks about perception – eliminating NIAAA as an institute gives the perception of de-emphasizing alcoholism – and as others noted in their remarks, alcoholism is a much greater health hazard as well as burden on society than drug abuse.
7. Dr. Varmus made comments trivializing what it takes to do a merger. Having lived through GE Aerospace/Martin as well as Martin/Lockheed – from the lowly employee perspective – it is not trivial. And from your perspective I doubt that it was trivial. I saw untold hours of employees on the phone with contracts, benefits, - the infrastructure in general – trying to find the right connections, straighten out errors in paychecks, learn who the new counterpart is to get a desk moved etc. etc. In an NIH merger the problems will be different but I can anticipate trying to find out who the person is in charge of this lab or that lab and who needs to sign a requisition to replace a broken piece of lab equipment or buy more beakers or whatever. There is no getting around it – it is disruptive and remains so for an extended period of time.

I thank you for taking the time to read this letter and for your service to the country.

With great respect,
Peg Calder
President, Foundation for Alcoholism Research.

Heart Disease	61 million	CDC
Diabetes	23.6 million	CDC
Alcoholism	17.6 million	NIH
Cancer	11 million	ACS
Alzheimer's	5.3 million	Alzheimer's Association
AIDS	1.1 million	CDC
Parkinson's	.5 million	NIH
MS	.4 million	National MS Society



FASEB
Quality Life Through Research

Federation of American Societies for Experimental Biology

Member Societies

The American Physiological Society
American Society for Biochemistry and Molecular Biology
American Society for Pharmacology and Experimental Therapeutics
American Society for Investigative Pathology
American Society for Nutrition
The American Association of Immunologists
American Association of Anatomists
The Protein Society
Society for Developmental Biology
American Peptide Society
Association of Biomolecular Resource Facilities
The American Society for Bone and Mineral Research
American Society for Clinical Investigation
Society for the Study of Reproduction
Teratology Society
The Endocrine Society
The American Society of Human Genetics
Environmental Mutagen Society
International Society for Computational Biology
American College of Sports Medicine
Biomedical Engineering Society
Genetics Society of America
American Federation for Medical Research

Representing over 100,000 biological and biomedical researchers.

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December 6, 2010

Scientific Management Review Board
Office of the Director
National Institutes of Health
Building 1, Room 103
9000 Rockville Pike
Bethesda, MD 20892

VIA EMAIL TO: smrb@mail.nih.gov

Dear Scientific Management Review Board Members:

The Federation of American Societies for Experimental Biology (FASEB) would like to share its views on the pending recommendations of the National Institutes of Health (NIH) Translational Medicine and Therapeutics (TMAT) Working Group regarding the proposed translational medicine Institute or Center (IC). FASEB is the nation's largest coalition of biomedical scientists and engineers, representing 23 scientific societies and more than 100,000 researchers. The Federation and its member societies are actively involved in the effort to expedite the development of new therapies, and we strongly support the translational research goals articulated by the NIH Director and the Scientific Management Review Board (SMRB). The proposals put forth by the TMAT Working Group, however, are moving very quickly, and the scientific community has not had the time or the information to assess them properly. Changes of this magnitude need to be carefully considered. **We recommend that SMRB delay its transmission of the TMAT recommendations to the NIH Director to allow for a more substantive dialogue with all stakeholders and an analysis of the potential consequences of these changes.**

FASEB agrees that advancing the development of therapeutics should be a high priority for NIH. We question, however, whether the creation of a new translational research IC is the best way to meet that goal. Translational research, by its very nature, must draw upon the investment in basic research made by the various ICs. It is unclear to us how a new organizational entity will facilitate translation when the fundamental science is supported in the existing ICs. **In fact, the creation of a new entity could delay translation by creating a new bureaucratic structure that is cut off from the research base in the ICs.** The research community would appreciate more information on the role SMRB envisions for a TMAT IC with regard to funding translational research projects and how that role will be balanced with the work already being

conducted by the ICs. Without this additional information, we are not convinced that the expected outcomes justify the cost of the new center or the potential disruption of ongoing programs.

The TMAT Working Group's preferred option for reorganization calls for removing the Clinical and Translational Science Awards (CTSA) program from the National Center for Research Resources (NCRR) and combining it with other components of the NIH translational research portfolio to form the new TMAT IC. In addition to being concerned about the impact the proposed reorganization could have on the translational research supported by the other NIH ICs, we are concerned about the effect it may have on the other NCRR resources essential to the nation's biomedical research enterprise.

Before a final recommendation is made to the NIH Director, FASEB encourages SMRB to allow more time for a thorough dialogue with the extramural community and to examine the impact of reorganization on other components of the NIH portfolio. We hope that you will consider input from the broader research community as you evaluate these issues.

Sincerely,

William T. Talman, MD
FASEB President

Public comments: Formation of Translational Medicine and Therapeutics (TMAT) Program at NIH
Submitted by The Humane Society of the United States
December 7, 2010

Thank you for the opportunity to comment on the proposed formation of a center focused on translational medicine at the National Institutes of Health. The development of effective drugs and therapies is an important goal and of great interest to the general public, as well as to The Humane Society of the United States and our 11 million supporters.

Given the mandate and activities of the Scientific Management Review Board, the TMAT working group, and the subsequent relevance to the National Center for Research Resources (NCRR), this is an opportune time to draw attention to a program currently overseen by NCRR that is costly and ineffective—namely, the warehousing and use of chimpanzees in invasive research.

According to the TMAT, one goal is to promote "quick win, fast-fail paradigms" but the chimpanzee model is the very antithesis of a quick-win, fast-fail paradigm. Cutting-edge activities, such as high throughput screening programs (e.g. TRND, MLI) carried out by the NIH Chemical Genomics Center, are exciting, effective and forward-looking—chimpanzee research is expensive, of dubious effectiveness, and regressive.

NIH owns approximately 500 (and "supports" another 250) of the 1000 chimpanzees in laboratories today. According to Sally Rockey, Deputy Director of Extramural Research, $63 million was spent on chimpanzee research and maintenance in the most recent year. The reality is that an estimated 80-90% of these chimpanzees are not being used at any given time and, instead, are simply being warehoused at great expense to NIH.

The failure of the chimpanzee model for HIV research has been recognized and the pharmaceutical industry is now shifting away from chimpanzee use in the development of hepatitis C vaccines and treatments.

Different institutes and centers within NIH have been managing the government-owned chimpanzee colony at cross purposes at taxpayer expense. For example, NCRR has a policy against the breeding of federally-owned and supported chimpanzees, yet NIAID is funding the breeding of federally-owned and supported

chimpanzees—with each chimpanzee produced resulting in a $1 million future commitment by NIH for his/her life-time care.

The HSUS requests that the Scientific Management Review Board recommends:

1. that NCRR's policy against the breeding of federally-owned and supported chimpanzees be implemented immediately NIH-wide and be properly enforced;
2. that chimpanzee research and warehousing in laboratories be phased out and that all government-owned chimpanzees be retired to the national chimpanzee sanctuary system, starting with the 186 chimpanzees who are currently residing at the Alamogordo Primate Facility and haven't been used in almost 10 years. This will save money and provide the chimpanzees with a better life; and
3. that oversight of the national chimpanzee sanctuary system (and associated funding) be shifted to the Office of Laboratory Animal Welfare.

Adoption of these recommendations would not only free up valuable resources for the development of effective therapies but would save chimpanzees from suffering and give them a life that they deserve after decades (for many of them) spent in laboratories.

Thank you for your time and consideration of this important matter.

Sincerely,

Kathleen Conlee
Director of Program Management
Animal Research Issues

The Jackson Laboratory
Leading the search for tomorrow's cures

December 3, 2010

Mr. Norman Augustine, Chair
Scientific Management Review Board
NIH Building 1, Room 103
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smrb@mail.nih.gov

Dear Mr. Augustine and Members of the Scientific Management Review Board:

The Translational Medicine and Therapeutics Working group of 11/10/10 discusses progress in planning to speed the translation of basic research discovery to clinical practice. On behalf of The Jackson Laboratory, we applaud the goal. As a national research, education, and resource center for the biomedical research community, our faculty and staff are committed to participating in the transformation of medicine that will result from applying recent discoveries to the clinic. It is in our role as a nationally recognized resource center that we write to request that great care and thought go into how the divisions of NCRR that support basic discovery are handled in this reorganization to stimulate translational research.

In particular, we request that you consider including the Division of Comparative Medicine in the proposed new IC. The proposed goals to provide and support resources, training and tools to enable translational and therapeutics development research are a strong fit with the Division's mission to provide model organisms and information to researchers. This will be particularly important in the new IC's efforts to "amplify the connection between basic discovery and translation." Given the importance of model organisms in the pipeline for producing individualized therapeutics, it will be critical to coordinate the Division's model organism resources with the new IC's work to streamline the therapeutic development pipeline.

Two projects funded through revision awards to grants that support our mouse repositories (P40RR016049 and P40RR001183) exemplify the benefits of coordinating the CTSA program with the Division of Comparative Medicine. These collaborations leverage the strengths at each institution to speed the application of basic discovery to preclinical and clinical testing.

- **Investigating the biological consequences of aneuploidy in early embryogenesis,** a collaboration with University of Michigan Transgenic Animal Model Core Facility (UMTAMCF, a university ABMR), and several research groups affiliated with the Michigan Institute of Clinical Health and Research (MICHR, CTSA awardee) in a combined effort to (1) enhance our understanding of the early embryonic consequences of aneuploidy using several genetic mouse models and (2) develop new resources for studying aneuploidy.
- **Development of the bENaC model of cystic fibrosis for translational research**, a collaboration with the Cystic Fibrosis Research and Treatment Center at The University of North Carolina at Chapel Hill. The project aims to identify novel genetic modifiers of the *Scnn1b* mouse model for cystic fibrosis and develop the model for preclinical testing protocols. This work supports the translational research goals of the North Carolina Translational and Clinical Science (TraCS) Institute (an NCRR-supported CTSA).

Grants from NCRR support research and resources at many U.S. institutions. As an international resource center, we at Jackson can clearly see the breadth of research enabled by NCRR support. Long-term funding from NCRR for Jackson's resource mission is fundamental to our ability to serve the biomedical research community. Jackson has long been the primary resource for genetically defined mice for the national research endeavor, and a glance at our distribution history and statistics reveals the enduring and widespread utility of these NCRR-supported research reagents.

Our scientists have developed and distributed inbred and mutant strains of mice since the institution's inception. NCRR (formerly the Division of Research Resources) has funded the characterization and distribution of spontaneous mutations arising in our distribution colonies continuously since 1978. Thousands of mice representing spontaneous mutations resulting in disease phenotypes have been distributed from our NCRR funded repository. Along with the Mouse Mutant Resource, JAX and the NCRR established the Special Mouse Strains Resource (SMSR) for recombinant inbred (RI) and consomic strain (CS) panels in 2001. This resource has the largest collection of RI and CS sets in a single repository and distributes them to labs world-wide.

In 1992, at the request of the scientific community, Jackson developed the first national repository for transgenic and targeted mutant mice, ensuring the preservation, genetic and health quality, and distribution of the rapidly expanding numbers of mouse models for human diseases. This Induced Mutant Resources was at first funded through private foundations, and since 1993 by grants from NCRR. Of the over 2000 mutant strains the Induced Mutant Resource has imported and developed, most have been cryopreserved, nearly half are maintained in breeding colonies, and many hundreds of thousands of mice have been distributed to biomedical researchers world-wide. Our experience with the Induced Mutant Resource paved the way for the NCRR-funded Mutant Mouse Regional Resource Centers (MMRRC) and other international resources, with whom we collaborate. The Division of Comparative Medicine is an influential leader in efforts to make these valuable research reagents available rapidly and cost-effectively.

It would not have been possible for us to manage this ever-increasing number of strains without continuous funding since 1981 from the Division for our cryopreservation research and resources. Advances in the ability to reliably recover embryos from diverse inbred and mutant strains of mice enabled us to preserve mice in low demand. Recognizing the crucial role of cryopreservation in managing the exponentially increasing number of new animal models, the Division of Comparative Medicine co-organized a workshop at NIH in April 2007 entitled "Achieving High-Throughput Repositories for Biomedical Germplasm Preservation." The results of this workshop guided the funding priorities that have supported breakthroughs in cryopreservation here and elsewhere that now make possible efficient management of large numbers of small colonies of specialty mice.

Our specialty colonies have now been combined into *The Genetic Resource Science (GRS) Repository,* which maintains more small colonies of live mice than all other U.S. public repositories combined (determined from queries of public web sites). Although a number of disease-specific agencies fund small colonies within the Repository, the majority of the funding for new strain acquisitions is supported by NCRR. Maintenance and distribution of mice are self-supporting. Typically, the GRS Repository has approximately 1,500 live strains on the shelf available for distribution at any one time. The size of individual colonies is constantly monitored and adjusted according to demand within a fixed capacity. Requests for breeder pairs and small cohorts of mice are fulfilled, with larger experimental groups available by special arrangement. The thousands of Repository mice distributed reflect both the value of this resource to the community and the efficiency of distribution operations. The number of live mice distributed from the Repository annually has steadily grown from about 40,000 in FY2006, to 85,853 in FY2010. The average processing time from request to shipping has remained at 2-4 weeks in spite of this increased demand.

Today, three fourths of the 5,000 mouse strains distributed by Jackson are managed exclusively as cryopreserved embryos, sperm, or ovaries, saving $14 million per year in operating costs while ensuring the availability of these vital resources in perpetuity. During the most recent 6 months, the Reproductive Sciences group:

- Filled 583 orders for cryopreserved materials including ES cells, mouse embryonic fibroblasts, tissue, sperm, and embryos;
- Recovered 1,200 strains from cryopreserved embryos or sperm for orders or as part of QC processes;
- Produced 18,000 mice to fill 917 orders from 27 countries for strains that had been cryopreserved.

This scope of resource provision would not have been possible without support from NCRR.

In addition to the major support of mouse resources, funding from other NCRR divisions is essential for our ongoing research and training endeavors that underlie our ability to characterize the genomes and phenotypes of the research resources we distribute. Eleven shared instrumentation grants from the Division of Biomedical Technology have purchased equipment including a range of advanced microscopes, flow cytometry and blood chemistry analyzers, first and second generation DNA sequencers, and a spectral karyotyping system. These instruments have been used to characterize models of a variety of human diseases including neurosensory loss, infertility, cancers, sickle cell anemia, metabolic diseases, neurological disorders, kidney disease, and immune disorders, among others. Fourteen grants from the Division of Research Infrastructure have supported improvements to our research animal facilities that house the Repository colonies, our quarantine facility, and laboratories for phenotypic characterization of mouse models. The Division of Research Infrastructure also supports the IDeA program, including the INBRE program, in which Jackson participates to offer students from Maine institutions access to our internship and workshop programs. We strongly urge you to maintain the full function of these vital national resource providers in any reorganization plan you undertake.

Thank you very much for your consideration of our request. NCRR's role in providing resources for basic and translational researchers is crucial to the success of efforts at NIH to advance therapeutic development. In particular, the role of the Division of Comparative Medicine in developing appropriate resources and stimulating interactions among basic and translational scientists merits its inclusion in a new IC for translational medicine.

Sincerely,

Robert Braun, PhD, Associate Director/Chair of Research

Leah Rae Donahue, PhD, Director Genetic Resource Science

Valerie Scott, Senior Director, Scientific Services

David Valle, MD, Chair, Board of Scientific Overseers
Henry J. Knott Professor and Director, Institute of Genetic Medicine, Johns Hopkins University School of Medicine

David Burke, PhD, Chair, Genetic Resource Science Advisory Board
Professor of Human Genetics, University of Michigan Medical School

cc: Dr. Francis Collins
Dr. Lawrence Tabak

UNIVERSIDAD DE PUERTO RICO, RECINTO DE CIENCIAS MEDICAS
UNIVERSITY OF PUERTO RICO, MEDICAL SCIENCES CAMPUS
Unidad de Medicina Comparada
Unit of Comparative Medicine

Edmundo Kraiselburd, PhD
Professor and Director

December 2, 2010

Dr. Lyric Jorgensen
smbr@mail.nih.gov
Office of Science Policy
Office of the Director, NIH
6705 Rockledge Dr. Suite 750
Bethesda, MD 20892

Dears Drs Rubenstein and Jorgensen:

NCRR supports 480 scientific and infrastructure projects in Puerto Rico, representing 35% of all active NIH-supported grants. The Caribbean Primate Research Center (CPRC) belongs to the University of Puerto Rico and receives support from NCRR (NIH). The Center has many active research projects, and collaborates with the National Primate Research Centers. CPRC houses the second largest SPF rhesus colony in the nation. This SPF colony and our conventional animals are the platform of many translational research projects, all funded by NIH.

I understand that a proposal to move the CTSA programs out of NCRR is under consideration. I believe that this proposal, which aims to form a new NIH Institute, should address the critical issue of the fate of NCRR, and the impact that this could have on all NIH-funded programs. In particular, I sincerely hope that NCRR's Comparative Medicine Program will not be broken up among Institutes, for the benefit of all research resource programs that support biomedical research in our Nation.

Sincerely yours,

Edmundo Kraiselburd, PhD
Professor and Director
Unit of Comparative Medicine
Caribbean Primate Research Center
University of Puerto Rico

ATTACHMENT 8c

As a Principal Investigator for one of the Clinical and Translational Science Award (CTSA) sites, I was concerned that the models of translation in slides 27 and 28 did not explicitly include the full continuum of research translation that spans T1 through T4, including comparative effectiveness research (CER) and community engagement. As these areas represent two of the six required core support areas for CTSA Centers as described in NCRR's latest RFA, I strongly feel they should be represented in any potential reorganization of the translational science enterprise at the NIH.

Sincerely,
Don McClain MD, PhD
University of Utah

Dear Francis and Lyric,

It will be devastating to disintegrate an institute such as NCRR since it promotes basic sciences at its resources and have proven to be a very well functional institute.
As laboratory animal medicine veterinarian, veterinary pathologist, scientist and US citizen, I am against the pulling of the CTSAs programs out of the NCRR and the possibility of the disintegration of the NCRR.

Andres Mejia

--

Andres F. Mejia, D.V.M., M.S., DACLAM

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MMRRC
Mutant Mouse
Regional Resource Centers
supported by NCRR-NIH

3 December 2010

Mr. Norman Augustine, Chair
Scientific Management Review Board
NIH Building 1, Room 103
9000 Rockville Pike
Bethesda, MD 20892
smrb@mail.nih.gov

Dear Mr. Augustine and Members of the Scientific Management Review Board:

We, the Principal Investigators and Co-investigators of the Mutant Mouse Regional Resource Centers (MMRRC), write with respect to the Translational Medicine and Therapeutics (TMAT) Working Group's 11/10/10 report on enhancing the rate at which discoveries made by basic biomedical research are translated to clinical research and, ultimately, therapeutics. We commend the TMAT on its efforts to enhance the infrastructural resources that support translational research, medicine and therapeutics with the Clinical and Translational Science Award (CTSA) program serving as a nucleus. The recommendation to create a new NIH institute is a bold approach. We understand this report will be discussed and voted on in the 7 December meeting of the Scientific Management Review Board (SMBR) and would like our suggestions below to be taken into consideration in your deliberations.

Currently, as you well know, the CTSAs reside in the National Center for Research Resources (NCRR). If the TMAT Working Group's proposal is approved, we urge you to consider carefully the disposition of other programs within NCRR that also provide infrastructure for translational research. Specifically, please consider moving NCRR's Comparative Medicine program to the new institute with the CTSAs. Animal model resources are critical to the infrastructure that supports translational research and therapeutics. Basic biomedical research is the foundation stone for translational medicine. As we all know, basic biomedical research, which uses these animal model organisms, makes the discoveries that enable us to understand disease processes and lead to the development of new treatments. Model organisms, particularly mice, rats and non-human primates, play a key role not only in basic research discoveries but also in initial testing of therapeutics.

The NCRR's Division of Comparative Medicine has taken several key initiatives to enhance the goals of Translational Research. For example, in 1999 it established the Mutant Mouse Regional Resource Centers (MMRRC) program. The MMRRC enhanced the accessibility of mouse models for biomedical research by establishing regional resource centers for important mouse models of human disease. The MMRRC also provide centralized resources that carry out research to improve delivery of resources, such as improved cryopreservation technology. With stimulus money in 2009 the Division of Comparative Medicine provided revision (supplemental) funding that linked research resources in animal model programs supported by Comparative Medicine with the CTSAs to facilitate more rapid transfer between basic research and translational medicine. Examples of such revision awards:

The University of Missouri was awarded two CTSA-linked grants.

1. A revision for their National Swine Research and Resource Center (NSRRC) award that funds a collaboration between the NSRRC and Duke University for Evaluation of New Therapeutic Compounds for Treatment of Urinary Tract Infections.
2. A revision to their Rat Resource & Research Center (RRRC) that supports collaborations with several CTSA-funded institutions including Utah State and Duke University. On-going projects include Investigation of Induced Pluripotent Cells for Translational Research.

The Jackson Laboratory was awarded two supplements to grants that support their mouse repositories.

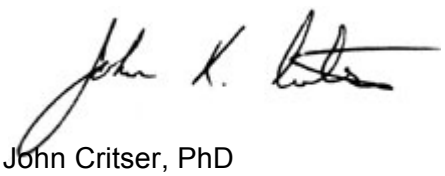
1. A revision to the Mouse Mutant Resource that funds a collaboration with the University of Michigan Transgenic Animal Model Core Facility (UMTAMCF, a university ABMR), and several research groups affiliated with the Michigan Institute of Clinical Health and Research (MICHR, CTSA awardee) in a combined effort to (1) enhance our understanding of the early embryonic consequences of aneuploidy using several genetic mouse models and (2) develop new resources for studying aneuploidy.
2. A revision to the Special Mouse Strains Resource that funds a collaboration with the Cystic Fibrosis Research and Treatment Center at The University of North Carolina at Chapel Hill to identify novel genetic modifiers of the *Scnn1b* mouse model for cystic fibrosis and develop the model for preclinical testing protocols. This work supports the translational research goals of the North Carolina Translational and Clinical Science (TraCS) Institute (an NCRR-supported CTSA).

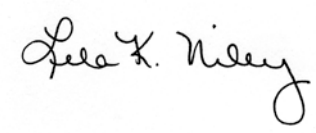
These revision awards and other Comparative Medicine programs have stimulated collaborations between CTSA translational investigators and basic animal resource scientists.

We are concerned that, if the CTSAs move out of the NCRR, such Comparative Medicine programs will be in jeopardy. The laudable goals for the new institute include “identify and bridge gaps,” “amplify the connection between basic discovery and translation” and “facilitate effective transition between steps.” Such existing programs that connect animal model resources with translational medicine resources position the animal model programs ideally to continue to collaborate with the CTSA program proposed as the heart of the new institute. Transferring the infrastructure for animal models research and translational medicine to the new institute together will build on connections already made to achieve the institute’s goals. In its wisdom NIH created the NCRR to centralize funding for research resource programs whose infrastructure supports research across many NIH categorical institutes, and to free the categorical institutes to focus, rightfully, on research on specific human diseases. Keeping the CTSAs and the animal model resource programs together in a new institute will preserve this goal in the new institute.

Thank you for considering our comments on the goals and implementation of the new NIH institute. We sincerely hope that the points we have made will encourage you to include the Division of Comparative Medicine’s animal model infrastructure programs within the new institute for Translational Medicine and Therapeutics.

Sincerely,





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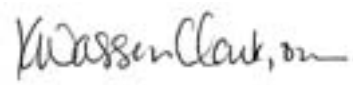
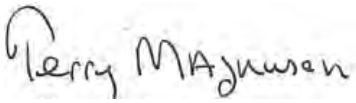
MMRRC at University of Missouri

Lela K. Riley, PhD
MMRRC at University of Missouri

Kent Lloyd, DVM, PhD
MMRRC at University of California, Davis



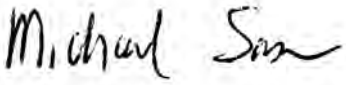
Kate Wasson Clark, DVM, PhD
MMRRC at University of California, Davis



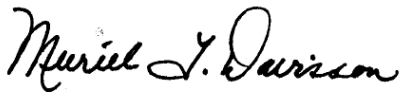
Terry Magnuson, PhD
MMRRC at University of North Carolina

Scott Bultman, PhD
MMRRC at University of North Carolina

Leah Rae Donahue, PhD
MMRRC at The Jackson Laboratory



Mike Sasner, PhD
MMRRC Informatics and Customer Service Center



Muriel Davisson, PhD
MMRRC Informatics and Customer Service Center

cc: Dr. Francis Collins (francis.collins@mail.nih.gov)
Dr. Arthur Rubenstein, Chair, TMAT working group (AHRdean@mail.med.upenn.edu)

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December 6, 2010

Francis S. Collins, M.D., Ph.D.
NIH Director
National Institutes of Health (NIH)

Dear Dr. Collins,

I have heard about the current proposal by the Scientific Management Review Board (SMRB) to transfer the Clinical Translational Science Award (CTSA) program from the National Center for Research Resources (NCRR) and award it to a new institute. My collaborators and I are very concerned implementing such a proposal will negatively affect the NCRR and more specifically impact the important work being overseen by the Division of Comparative Medicine (DCM).

I am using small fish, such as zebrafish and medaka as animals models to identify the molecular mechanisms of cardiovascular system development and the developmental abnormalities caused by the dysfunction of cytoskeletal genes as human disease model.

Information from my basic research using these animals may help us develop procedures and techniques that will alleviate or prevent ovarian cancer, congenital heart disease, and other related maladies. Without funding, the potential to combat these often deadly conditions will become seriously endangered.

It has become frightening for us and for many within the community of scientists who utilize aquatic research models the think that NIH might remove its focus from comparative medicine research by separating the NCRR and/or DCM. We wonder if the fragmentation of the function of the DCM may result in loss of many important animal research resources and aquatic models.

Such a situation will decrease our national capability to tackle future biomedical problems that simply cannot be accomplished by using only the three or four mammalian systems represented within the portfolios of standing NIH institutes. The DCM support for aquatic models research has been the single critical avenue that has ensured that these valuable models continue to develop and offer new insight into biomedical problems.

The reduction or elimination of funding would also have a disastrous effect upon the numerous groups of scientists and there teams that are presently engaged in ongoing research. Research groups are not merely a collection of individuals; they composed of people with diverse talents who have learned to work together over time as a functioning group. Everyone has benefitted from the experience of this long term association within the various groups. I also strongly believe that this is not the time to break up scientific teams thereby

fragmenting the DCM expertise along with its resulting consequences for the organisms of comparative medicine as a independent organisms which need to be maintained under individual administrative oversight.

If the support were to be lost or reduced, it means we would also be unable to support those who are involved in our medical research projects. In our communities, many students who are presently working hard and are highly motivated in their pursuit of medical research may be forced to find employment elsewhere; it may take a considerable amount of time to recover the loss of this human potential.

If our students are unable to continue with their research, we risk losing not only their present participation, we risk losing them completely to other endeavors. If this happens, we may lose not only a generation of young researchers; the consequence of their loss may extend far into the future.

Once we have lost quality people and therefore, our competitive power in international medical research may take decades to rebuild. We must continue to support technical and scientific advancements as well as continue to meet the needs of the educational aspects of scientific research. This is not the time for the NIH to turn away from its commitment to comparative medicine.

The newly developed “next generation” sequencing technologies have made it possible for large genomes and complex transcripts to be completely sequenced and assembled much faster and at a lower cost. These pioneering advancements have allowed scientists to use aquatic experimental models making it easier to achieve research goals in the field of comparative genomics and transcriptomic analyses which is at the forefront of international biomedical research efforts. Comparative medical research has contributed to the understanding of the molecular mechanisms of diseases and abnormalities caused by genetic disorders. This research has supplied us with a further understanding of how each unique organism and cell has evolved by adapting to the environment to sustain its life.

Please consider this as you determine how best to proceed. The seeds of scientific discovery that incite biomedical research are often grown in alternative experimental models.

As one of the scientist using the aquatic animal models, I would like to request that NIH not to allow other issues to contribute to the eventual elimination of DCM, one of the better programs in the NIH.

Sincerely,

Kenji Murata (Ph.D)
Department of Animal Science
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NAEVR
National Alliance For
Eye And Vision Research
Serving as Friends of the National Eye Institute

1801 Rockville Pike
Suite 400
Rockville MD 20852
240-221-2905; www.eyeresearch.org

Public Statement Regarding Creation of a New Translational Research Center
NAEVR Executive Director James Jorkasky
Scientific Management Review Board (SMRB) Meeting
Translational Medicine and Therapeutics (TMAT) Working Group
December 7, 2010

Thank you, Chairman Augustine. I am James Jorkasky, Executive Director of the National Alliance for Eye and Vision Research, or NAEVR, which serves as the privately funded ""Friends of the National Eye Institute (NEI)." NAEVR is a research advocacy organization that does not speak for NEI, but about its accomplishments. I want to speak briefly about retaining Institute/Center (I/C) flexibility in translational approaches.

In September, I testified before you about NEI's collaborations within the NIH, across the Department of Health and Human Services (DHHS), with other government agencies, with private funding organizations, and internationally in translational research. The NEI has been recognized by Dr. Collins for its leadership in this regard.

Although the NEI is a relatively small Institute, it has conducted numerous translational collaborations that have smartly and effectively expanded its research dollars. NEI's translational research has resulted in drugs and devices─ and combinations thereof─as well as diagnostics and gene therapy approaches, reflecting the promise of translational research to offer a "rich repertoire of patient solutions."

In summary, as the SMRB/TMAT proceeds in deliberations and in offering a recommendation, and as the NIH studies the implications of a new Translational Research Center for the I/Cs, all should adhere to one of the characteristics that the TMAT has described for such a Center −that it promotes and allows flexibility in decision-making and priority-setting. Although centralized decision-making could provide additional opportunities and economies of scale, especially for mid-to-small-sized I/Cs, it should not stifle their creativity in pursuing innovative translational research approaches.

Thank you for this opportunity for NAEVR to once again provide its input.

National Advisory Research Resources Council
Letter to the NIH Scientific Management Review Board

30 November 2010

Mr. Norman Augustine
Chair, Scientific Management Review Board, OD, NIH
Building 1, Room 103
9000 Rockville Pike
Bethesda, MD 20892

Francis S. Collins, M.D., Ph.D.
Office of the Director, NIH
Building 1
9000 Rockville Pike
Bethesda, MD 20892
National Institutes of Health

RE: NARRC response to TMAT recommendations to SMRB

Dear Mr. Augustine and Dr. Collins,

We are writing on behalf of the National Advisory Research Resources Council (NARRC), an independent advisory body for the National Center for Research Resources (NCRR), with members appointed by the Secretary of HHS (http://www.ncrr.nih.gov/about_us/advisory_council/roster.asp). The NARRC has a clear understanding of the NCRR portfolio, and we have now reviewed the recent (11/10/2010) recommendations of the SMRB's Translational Medicine and Therapeutics (TMAT) working group. The primary TMAT recommendation, to be presented to the SMRB at its upcoming meeting (12/7/2010), is creation of a new NIH IC for Translational Medicine and Therapeutics. The principal component of the new IC would be the NCRR's Clinical and Translational Science Awards (CTSAs), initiated by the NCRR in 2006 (FY2010 $464.8M). The continuation or dissolution of the NCRR itself is not clearly addressed, leaving open many related questions concerning possible elimination or reassignment of other programs in the current NCRR portfolio.

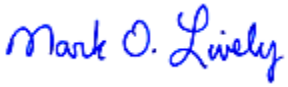
The mission of the NCRR is unique at the NIH, providing flexibility and independence not easily available in categorical ICs. Aside from clinical projects such as CTSAs, NCRR divisions include: Research Infrastructure ($306.3M); Comparative Medicine ($196.9M); Biomedical Technology (FY2010 $181M); Small Business Grants ($33.6M); and Science Education Partnership Awards ($18.6M). The combined non-CTSA NCRR budget thus amounts to roughly $736M, larger than the budgets for half of the other NIH ICs. Furthermore, the NCRR is uniquely responsible for funding and managing extramural construction, currently more than $1B.

In view of these issues, the NARRC strongly urges the SMRB and Office of the Director to delay any decisions based on TMAT recommendations that affect NCRR programs. Possible changes to existing NCRR programs must involve further open discussion with the scientific community, as well as the other NIH ICs. Strong consideration should be given to continuation of the NCRR as a free standing center. Regardless, additional discussion is essential for deliberate and transparent consideration of the NCRR and all components of its existing portfolio.

Sincerely, Members of the NARRC,

National Advisory Research Resources Council
Letter to the NIH Scientific Management Review Board

Signatories



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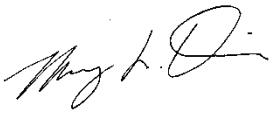

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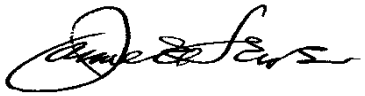

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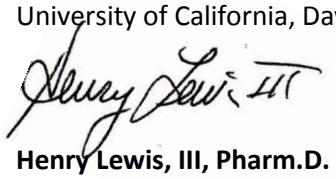

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Janet L. Smith, Ph.D.
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National Advisory Research Resources Council
Letter to the NIH Scientific Management Review Board

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Director, Office of Economic Innovation and Partnerships
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M. Christine Zink, Ph.D., D.V.M.
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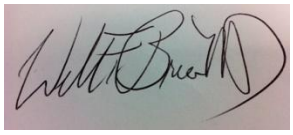

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Shriners Hospitals for Children

David Flockhart, M.D., Ph.D.
Gladstein Chair in Cancer Genomics
Professor of Medicine
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cc: Barbara M. Alving, MD, Director, NCRR

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National Primate Research Center Consortium
Statement on the Critical Role of Primate Centers in Translational Research
Submitted to the
National Institutes of Health (NIH) Scientific Management Review Board (SMRB) Translational Medicine and Therapeutics (TMAT) Working Group
November 19, 2010

The National Primate Research Center (NPRC) Consortium is pleased to submit the following statement outlining how the eight National Institutes of Health (NIH)-supported NPRCs are integral to translational medicine and therapeutics activities at NIH. **The NPRC Consortium requests that as the Translational Medicine and Therapeutics Working Group develops recommendations on organizing NIH's components to optimize translational research, it incorporate NPRCs into the new NIH translational medicine program to ensure our resources and capabilities are maximized for the improvement of human health.**

Supported by the National Center for Research Resources (NCRR), NPRCs are vital research centers that provide biomedical and behavioral investigators with access to valuable animal models, as well as expert consultation on utilizing these models to advance the aims of their research projects. As the model most closely related to humans, non-human primates are key components of basic and translational research funded by each NIH institute and center, and of important trans-NIH initiatives, such as Clinical and Translational Science Awards (CTSAs). In particular, non-human primates are essential to bridging the gap between basic, discovery science and the development of safe and effective treatments and therapeutics for patients, providing proof-of-concept that is frequently needed for clinical development.

Recently, the NPRC Consortium, in coordination with NCRR, embarked on the development of an NPRC strategic plan. At the center of this plan are scientific priorities that drive translational work into better interventions and diagnostics for improved human health. Thus, the future direction of NPRCs is based upon the scientific strengths and capacity of the consortium as a whole and is geared toward enhancing translational research and therapeutics development.

NPRCs offer scientific expertise, technologies, and unique infrastructure to advance translational research. Studies in non-human primates are essential to advancing therapeutics development, as they are indispensible models for human responses to many new pharmaceuticals, biotechnology products, cell and tissue transplants, gene transfer and targeting methods, surgical approaches, and diagnostic procedures and technologies. The NPRCs also expand biomedical informatics approaches to support research. We believe that biomedical informatics management is one of the biggest challenges facing NIH as it seeks to organize its translational medicine program, and NPRCs have developed new methods to collect, store, and share the information produced by non-human primate studies. The NPRCs believe that by working more closely with NIH, these data resources can be more efficiently integrated into the biomedical informatics network that informs translational research activities.

In addition to having an integral role in NIH's translational research activities, the NPRCs are significantly involved in activities tied to the other themes identified by Director Francis Collins. Of note, the Centers are leaders in the development and application of high throughput technologies to animal model systems, in addition to data storage. In relation to global health, the Centers provide direct support for human and animal health studies, as well as education and conservation efforts with international academic partners. The Centers also have a long-standing commitment to the mentorship and development of young researchers through training and fellowship programs at all of our locations. Some of these trainees are physician scientists who see patients on a regular basis, but want additional training in basic sciences and greater access to preclinical non-human primate studies. A subset of these physician scientists become staff scientists at the NPRCs and participate in translational research.

The eight NPRCs have long been focused on moving basic research into discoveries that will impact specific diseases and conditions. A 2010 survey of the eight NPRCs revealed that each has a variety of research foci that span the breadth of human diseases and conditions, including, autism; Alzheimer's disease and other neurodegenerative diseases; basic immunology and immunopathogenesis; cancer; substance abuse; Parkinson's disease; fertility and infertility; heart disease; diabetes and metabolic syndrome; obesity; bone-related diseases; stem cell therapies; psychological and behavioral disorders; gamete biology; cell and gene-based therapies; maternal-fetal health; asthma; infectious diseases, such as HIV/AIDS, hepatitis, tuberculosis, and malaria; and broadly applicable vaccine and therapeutic development programs.

NPRCs provide functional capabilities that enable NIH-supported researchers to accelerate research and therapeutic discovery. Non-human primates are an important tool to better understand human diseases and facilitate the development of effective interventions. The NPRCs together are a coordinated infrastructure with a shared goal of accelerating progress in understanding human disease, leading to better health. Our collaborative nature allows for integration with other NIH resources, such as CTSAs. It is important that the NPRCs' long-standing and ongoing central role in translational research be recognized and incorporated into the new NIH translational medicine program.

The UNIVERSITY of VERMONT
DEPARTMENT OF ANATOMY AND NEUROBIOLOGY

December 3, 2010

Arthur Rubenstein, M.B.B. Ch.
Chair, Translational Medicine and Therapeutics Working Group
Scientific Management Review Board

Dear Dr. Rubenstein:

I am writing to strongly urge that the IDeA and RCMI programs currently housed in NCRR remain intact and reside in the same institution in order to retain the synergies and impact in future years. The IDeA program is very highly regarded by Vermont's legislators and congressional representatives; both groups understand how important the IDeA programs have been to the growth of research and training opportunities at the University of Vermont (UVM) and other institutions throughout the state, along with their significant economic impact.

As PI of the Center of Biomedical Research Excellence in Neuroscience (Neuroscience COBRE) (NCRR P20 RR016435) at UVM, I can personally attest to the impact of the IDeA programs at our institution. Until the Neuroscience COBRE was awarded in 2001, neuroscience research and graduate training at UVM was not an identified area of strength recognized by the UVM Administration. Rather, it was primarily a faculty-driven series of research endeavors and graduate training programs diffusely scattered in departments across multiple colleges on the UVM campus. The Neuroscience COBRE significantly increased the infrastructure supporting neuroscience research and training on this campus. It created two key multi-user research Cores that have provided access to sophisticated imaging and molecular biology expertise and equipment not previously available to the UVM neuroscience community. The Neuroscience COBRE-supported research cores broaden research capabilities of faculty and complement, but do not duplicate other core facilities on the campus. Access to these core facilities has increased the competitiveness of neuroscience faculty for extramural funding. The Neuroscience COBRE also has supported recruitment of new neuroscience faculty in both basic and clinical departments and fostered the research endeavors of junior faculty until they attained independent extramural funding. Multiple new NIH grant awards are directly attributable to having had Neuroscience COBRE funding. The faculty and project support also has increased the number of science-related technical positions in the community, many of which have been filled by recent science graduates either from UVM or Vermonters returning home from out-of-state colleges. In a state with a small population and significant graying due to lack of good jobs for young people, these jobs have a substantial impact on our economy.

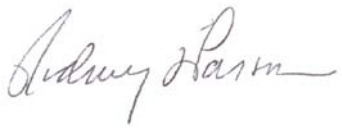
The Neuroscience COBRE award also was instrumental in facilitating the development of a University-wide Neuroscience doctoral graduate program. This program has been heralded by Dr. Daniel Fogel, President of UVM, as a model for the type of interdisciplinary graduate training programs he wants to develop at this institution.

The presence of the Neuroscience COBRE also contributed significantly to the selection of Neuroscience, Behavior and Health as one of the three Spires of Research Emphases at UVM. The selection process included evaluation by an elaborate internal review process and review by a committee comprised of very accomplished external reviewers.

Overall, the impact of the Neuroscience COBRE at UVM has been so significant that Neuroscience is now one of the strategic areas of research emphasis and graduate training at UVM. Its presence has been a key asset in recruiting both clinical and basic neuroscientists to our institution and has fostered translational neuroscience investigation. I encourage that the IDeA programs remain intact. I also recommend that if Clinical COBRES are made available in the future, that they should remain within the parent program.

I appreciate having an opportunity to provide input on this important issue.

Sincerely,



Rodney L. Parsons, PhD.
Professor and Chair

cc: Lyric Jorgenson, PhD, Office of Science Policy, National Institutes of Health
Francis Collins, MD, PhD, Director, National Institutes of Health
Patrick Leahy, JD, United States Senator for Vermont

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PEDIATRIC ENDOCRINE SOCIETY
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December 4, 2010

Scientific Management Review Board
ATTN: Lyric Jorgenson, PhD
Office of Science Policy, Office of the Director
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

Dear Scientific Management Review Board:

The Pediatric Endocrine Society is the largest U.S. organization dedicated to advancing the care of children and adolescents with endocrine disorders – including diabetes, obesity, growth disorders, and many other conditions. Translational research is critical to achieving this goal. We are writing to offer comments to the National Institutes of Health (NIH) and its Scientific Management Review Board (SMRB) on recommendations for integrating translational research at NIH.

On November 10, 2010, the Translational Medicine and Therapeutics (TMAT) Working Group of the SMRB outlined its proposal for a new institute or center (IC) to be formed to promote translational research across the NIH. The full board intends to vote on specific working group recommendations on December 7, 2010. We applaud the NIH for its dedication to furthering the translation of basic scientific advances into meaningful therapeutics for patients, and we urge the board seriously consider the needs of children as it considers recommendations for reorganization.

We believe that a specific focus on children's needs in the proposed reorganization is needed since (1) many pivotal issues in translational research are unique to children and adolescents and (2) data from adult trials and comparative research studies generally cannot be applied to children.

Therefore, we support the NIH's efforts to promote translational research. We also support the suggestions of the American Academy of Pediatrics, The Society for Pediatric Research, and other Pediatrics organizations urging the board affirm its commitment to child health by including following recommendations in any reorganization contemplated by the board: (1) any new structure should specifically establish child health research as a key priority; (2) a new IC for translational research should support and promote the important role of NICHD and the CTSA Child Health Oversight Committee in advancing child health

research; (3) the new structure should be cognizant of ongoing child health research conducted at NICHD and in other institutes and should work to facilitate translational research relevant to children across the institutes; and (4) recognizing the clear need for training the next generation of clinical and translational research professionals with expertise in children, a reorganized translational research infrastructure should maintain its commitment to research training and career development programs.

Thank you for your consideration of our comments. We look forward to working with you to improve child health. Please do not hesitate to reach out to us as you move forward with your plans.

Sincerely,

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UNIVERSITY OF PUERTO RICO, MEDICAL SCIENCES CAMPUS

Programa RCMI
RCMI Program

December 1, 2010

Scientific Management Review Board, OD, NIH
ATTN: Lyric Jorgenson
Office of Science Policy, Office of the Director
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

Dear Scientific Management Review Board:

This communication responds to the request for written comments on the recommendations from the Translational Medicine and Therapeutics (TMAT) working group, as published in the Federal Register's announcement for the December 7th Meeting of the Scientific Management Review Board.

Although encouraged by the hard work of the (TMAT) working group to expand and augment NIH's efforts in developing new therapeutics and enhancing clinical research infrastructure, as directors of the Research Centers in Minority Institutions (RCMI) Program at the University of Puerto Rico Medical Sciences Campus, we are extremely concerned about the potential negative impact of the proposed reorganization on the non-clinical research programs at NCRR. Our concern is reinforced by the fact that the evaluation of such impact was outside the mandate of the TMAT working group.

As an example, the RCMI Program has been committed to the development of a robust biomedical research infrastructure at minority institutions for over twenty-five years, diversifying the national capability for research in the health sciences. In addition to offering direct support for research infrastructure at these institutions, the RCMI Program has developed other mechanisms such as the Translational Research Network, RTRN, and the Infrastructure for Clinical and Translational Research, RCTR, to address the full spectrum of translational research, and is continually pursuing new and innovative ways to enhance opportunities for faculty at RCMI grantee institutions to partner and collaborate with investigators supported by other NCRR and NIH components, and other PHS agencies. How these efforts will be protected or continued after the proposed NCRR reorganization is unknown.

The uncertainties emerging from the proposed reorganization lead us to conclude that the creation of a new center for translational medicine requires a careful evaluation of the long-term effects on all NCRR-supported programs. This evaluation should be performed in close consultation with relevant stakeholders to ensure minimal negative impact on important programs and protection of current research alliances and partnerships. Such evaluation should also consider keeping together those programs with similar missions and targeted communities. In summary, more time for reflective and inclusive discussions is necessary to arrive at decisions that will be well received and assure long-term success for all involved.

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We respectfully request that our concerns be taken into consideration during deliberations next week on the recommendation of the TMAT working group.

Sincerely,

Emma Fernández-Repollet, Ph.D.
RCMI Program Director

José G. Conde, M.D., M.P.H.
RCMI Associate Program Director

c Francis Collins, MD, PhD, NIH Director
Norman Augustine, BSE, MSE, NIH SMRB Chair

To: Director Francis Collins and the members of the Scientific Management Review Board,

I am writing to express my concern about the effects on the National Center for Research Resources of forming a new Institute for Translational Medicine and Therapeutics which might house the CTSA program. A widely held perception is that establishing a new IC for TMAT would require the elimination of a standing IC and that removal of the CTSA program from NCRR would make that IC a likely target for disestablishment.

The NCRR supports research resources which are vital to researchers funded by a wide variety of NIH institutes. Indeed one of the requirements for support by NCRR of a resource is that the resource serve scientists supported by multiple NIH Institutes. These resources involve both shared equipment and specialized animal colonies. These resource programs are supported by a number of funding mechanisms such as P40 and R24 awards which are generally not available from other institutes. In addition, NCRR supports a number of unique training programs for veterinary doctors interested in entering research. Clearly, DVM scientists are in short supply and are vital to the mission of translational research.

Many of us who operate and/or rely on these resources are very concerned about a break-up of NCRR which might leave these resource programs (particularly those within the Division of Comparative Medicine) without proper management or funding support. We believe these resources are vital to the translational mission of NIH and, like the CTSAs, should not be allied with a disease-specific institute. Given the essential role that animal models and animal resources play in translational medicine, there also seems to be merit in keeping the CTSAs and the animal resource and related programs together in the same institute.

Thank you for considering these concerns as you move forward with the mission of the SMRB.

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December 2, 2010

Mr. Norman Augustine, Chair, norm.augustine@lmco.com

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Statement by Senior Comparative Medical Scientists at Major Academic Centers to the National Institutes of Health Scientific Management Review Board

As senior Comparative Medicine scientists in several major research institutions, we have followed the deliberations of the Scientific Management Review Board (SMRB) with great interest. We appreciate the compelling need for an Institute or Center within the NIH framework to advance the development of therapeutics by coordinating these efforts and providing critical infrastructure. We also are well acquainted with many of the stakeholders in academia, private research institutions and industry whose work could be facilitated by the SMRB's decisions. For these reasons, we would like to share our expertise and our perspective of the impact your deliberations will have on the NCRR's Division of Comparative Medicine.

Comparative medicine programs are a key component of many medical schools, veterinary schools and academic (or other) research institutions that focus on biomedical research. As comparative medical scientists in major research institutions, we bring a comparative, integrated approach to biomedical research; this means that we are typically the front line for translational research. All translational research, whether it begins as basic science, medical device development, imaging technology, bioengineering, etc., at some point attempts to translate new, theoretical knowledge into an intact animal system before it can be utilized in humans. This translation, this "one medicine", is what we in comparative medicine do every day. We do not live or work in silos. Comparative medical scientists come from many disciplines: veterinary pathology, laboratory animal medicine, toxicology, pharmacology, basic sciences, and human medicine. We use our broad expertise to develop and utilize a range of animal models to identify ways to alleviate human suffering by developing new therapeutic and diagnostic approaches. Comparative medicine programs train many scientists in basic research. We provide our expertise and advice to our professional colleagues to help them navigate the development and regulatory process to create new therapies. Our former trainees, whose training was supported by NCRR's Division of Comparative Medicine, work at other biomedical research entities, in government positions at the NIH, CDC, FDA, USDA or in the pharmaceutical industry where they are responsible for the safety assessment of new compounds in the development pipeline. It is these partnerships to conduct and support biomedical research in academia and industry which make

comparative medicine such a critical part of translating new discoveries into real therapies and makes NCRR's Division of Comparative Medicine so vital to translational medicine.

The constituency that NCRR's Division of Comparative Medicine serves is far too broad for a single categorical Institute. In addition to the vitally important comparative medicine research and training programs, the NCRR also supports comparative medicine infrastructure needs and other shared resources used by many biomedical scientists engaged in translational medicine. Examples of some of these resources include: the Mutant Mouse Resource Centers, the Knockout Mouse Project, the Zebrafish Resource Center, the Drosophila Stock Center, *Caenorhaditis elegans* Genetic Stock Center, and the National Primate Research Centers. These are only a few of the resources provided through NCRR which do not fit easily into any categorical Institute. In fact, it was the recognition of comparative medicine's global impact on all the categorical Institutes and Centers that led to the creation of the original Division of Research Resources and why it was removed from the Institute of General Medical Sciences many years ago. We believe that decision was appropriate in its time, and we hope that an equally wise decision will result from the current deliberations in the new era of translational science.

As the Scientific Management Review Board continues its deliberations, we ask that appropriate veterinary input be included from comparative medical scientists as it considers the status of NCRR and also that the broad scientific community have the opportunity to comment on the proposed re-organization.

Sincerely,

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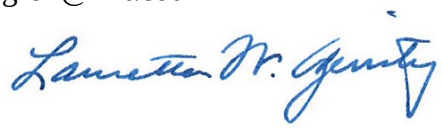

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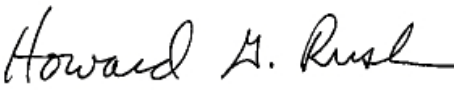

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Association for Patient-Oriented Research

Clinical Research FORUM
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SGIM
Society of General 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
Bethesda, MD 20892

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 CTSAs 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 CTSAs 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 CTSAs, 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 CTSAs 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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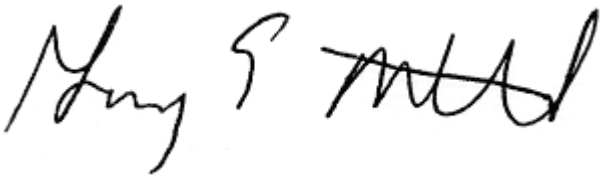

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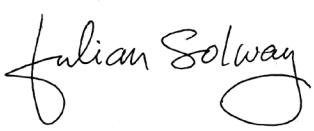

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cc: Dr. Francis Collins
Dr. Arthur Rubenstein
Dr. Norman Augustine

December 3, 2010

Scientific Management Review Board
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Bethesda, MD 20892

Dear Scientific Management Review Board:

As organizations dedicated to improving the health and well-being of children by furthering pediatric medical research, we write to offer comments to the National Institutes of Health (NIH) and its Scientific Management Review Board (SMRB) on recommendations for integrating translational research at NIH. On November 10, 2010, the Translational Medicine and Therapeutics (TMAT) Working Group of the SMRB outlined its proposal for a new institute or center (IC) be formed to promote translational research across the NIH. The full board intends to vote on specific working group recommendations on December 7, 2010. We applaud the NIH for its dedication to furthering the translation of basic scientific advances into meaningful therapeutics for patients, and we urge the board seriously consider the needs of children and families as it deliberates recommendations for reorganization.

Investments in the health of children are among the most valuable uses of public funds because they produce life-long benefits of increased well-being and productivity. Biomedical and behavioral research is the origin of the pediatric medical advances that deserve our support, and translational research is an essential piece of the process that brings these scientific developments into medical practice. This translation is especially important for children who are frequently left without the scope and quality of therapies that are available to adults. Effective translational research for children, however, would not be possible without infrastructure that recognizes the unique nature of children and supports pediatric efforts from basic science through phase 4 translational research.

The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) has been a critical partner in the effort to expand knowledge about disease that affects children and to develop medical advances to improve child health. Along with NICHD, the Clinical and Translational Science Awards (CTSA) Consortium has helped further child health by advancing clinical and translational research through investments in infrastructure and training programs. The CTSA Consortium Child Health Oversight Committee has been particularly valuable in ensuring that the CTSA program works for the benefit of children by supporting pediatric researchers and trainees.

We support the NIH's efforts to promote translational research and urge the board to affirm its commitment to child and family health by including the following recommendations in any reorganization contemplated by the board: (1) any new structure should specifically establish child health research as a key priority; (2) a new IC for

translational research should support and promote the important role of NICHD and the CTSA Consortium Child Health Oversight Committee in advancing child health research; (3) the new structure should be cognizant of ongoing child health research conducted at NICHD and in other institutes and should work to facilitate translational research relevant to children across the institutes; and (4) in recognition of the clear need for training the next generation of clinical and translational research professionals with expertise in children, a reorganized translational research infrastructure should maintain its commitment to research training and career development programs.

Thank you for your consideration of our comments. We look forward to working with you to improve child health by maximizing opportunities to translate advances into pediatric care. Please do not hesitate to reach out to us as you move forward with your plans.

Sincerely,

Academic Pediatric Association
American Academy of Pediatrics
American Pediatric Society
Association of Medical School Pediatric Department Chairs
Society for Pediatric Research

Statement Submitted for Consideration by the NIH Scientific Management Review Board at its Meeting on December 7, 2010 Regarding Potential Impact on NCRR Programs of TMAT Recommendations

We understand that, during your meeting on Tuesday, December 7, 2010, the SMRB will consider a proposal for a new NIH Center for Translational Medicine and Therapeutics that would likely involve transferring the CTSA portfolio currently within NCRR into the new Center, with implementation as early as the beginning of FY2012. Because planning for the new Center has proceeded so quickly, the stakeholders in other NCRR programs have not had an opportunity to provide adequate input on the consequences that could ensue for the remaining highly regarded elements of the NCRR portfolio. Because many other NCRR programs are strategically very important for future biomedical research and innovation and are uniquely found in the NCRR portfolio, we urge that much more detailed consideration be given to the potential deleterious impacts of the reorganization on these programs. Specifically, we would like to comment on programs in the NCRR Division of Biomedical Technology (DBT; http://www.ncrr.nih.gov/biomedical_technology/) with which we are most familiar.

The NCRR DBT coordinates, balances and stewards the Biomedical Technology Research Centers (BTRCs), a program which has been very successfully and professionally managed through the P41 grant mechanism over more than four decades. These high technology research centers have unquestionably been the broadest and most effective engines of invention supported by NIH, providing nationwide open access to cutting edge expertise and instrumentation. At the BTRCs, discoveries in the physical and computational sciences are translated into tools for biomedical research and the new technologies are disseminated through collaborative research and training activities with investigators supported by many of the other NIH institutes and centers. The BTRCs have a long history of productivity and of broad impact, especially with regard to new technologies that drive the national health agenda, with significant translational, clinical, and social impact and that expand the US economy through technology transfer. The BTRC Program has generated numerous advances and technological breakthroughs, including the first lab-based computers for real-time data processing (the forerunner of the personal computer), magnetic resonance imaging of organs including the human brain, synchrotron x-rays for structural biology and drug discovery, electron imaging of cells and nanomachines, peptide sequencing by mass spectrometry spawning the whole new field proteomics essential to deciphering genomics, multi-photon microscopy of cells and tissues dynamics, and optical and laser-based technologies for *in vivo* diagnosis and treatment. The current 48 BTRCs broadly support the national biomedical research and translational programs of more than 7,000 investigators whose research project support comes through peer-reviewed grant awards from 22 of NIH's institutes and centers. The BTRCs are highly regarded and well-established as the NIH's incubators for the invention, optimization and tailoring of new technologies so important to future medicine and to attracting and training the next generation of biomedical inventors and innovators.

Also among the unique NCRR DBT programs are the Shared Instrumentation Grant (SIG) and High End Instrumentation (HEI) programs, which provide support for the acquisition of state-of-the-art instrumentation for biomedical research that is not available through any other funding

source. Investigators supported by all the other NIH institutes and centers located in almost every state rely on these instrumentation programs for shared access to essential cutting edge technologies for their own biomedical research.

The BTRCs, and the NCRR Division of Biomedical Technology program staff that cultivate and manage these programs, have contributed to preeminence of the US in biomedical technology and have provided a model for national biomedical technology resource program development in Europe and Asia, where shared use of advanced facilities has begun to develop. Given the increasing role of new technologies in biomedical science and health care, we believe that any changes that would weaken these programs that foster technology development would be a significant step backwards for biomedical research in the US. It is our view that the BTRCs, together with the SIG/HEI program (and other smaller but complementary NCRR DBT programs), should be maintained under the umbrella of a cohesive, integrated and coordinated set of programs, housed in an NIH center or institute with the track record, expertise, and focus needed to effectively steward them. This is especially the case given the strategic value that they provide as the NIH engine of cross-disciplinary technology discovery and innovation.

If the SMRB recommends the formation of a new Translational Medicine and Therapeutics Center, it should also recommend that a process be expediently established to assure that sufficient time and attention are given to determine the impact of reorganization on the important and unique elements of the NCRR portfolio. This might be used as an opportunity to strengthen and expand these very successful technology development programs at a time when the innovation they represent is so crucial to the National agenda and shared resources optimize economic investment during times of constrained economic resources. Thank you for your consideration.

Respectfully yours,

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Dr. Wah Chiu, Distinguished Service Professor, Baylor College of Medicine, Houston, Texas 77030; wah@bcm.edu; Ph: 713 798-6985

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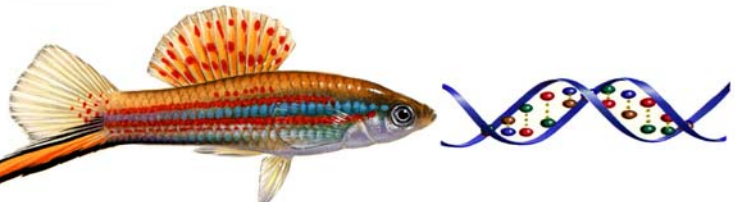
Dr. Keith Hodgson, David Mulvane Ehrsam and Edward Curtis Franklin Professor of Chemistry and Photon Science at SLAC, Stanford University, Stanford, CA 94305; hodgsonk@stanford.edu; Ph: 650 723-1328

Dr. Chris Johnson, Distinguished Professor of Computer Science, University of Utah, Salt Lake City, Utah 84112; crj@sci.utah.edu; Ph: 801 581-7705



Molecular Biosciences Research Group
Xiphophorus Genetic Stock Center

November 30, 2010

NIH Scientific Management Review Board
National Institutes of Health (NIH)

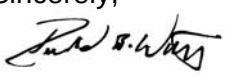
Dear SMRB Board Members:

I would like to address the current proposal by the Scientific Management Review Board (SMRB) to pull the Clinical Translational Science Award (CTSA) program out of the National Center for Research Resources (NCRR) and into a new institute. Many within the community of scientists that utilize aquatic research models are very concerned how adherence to such a proposal will affect the NCRR and more specifically the important work being overseen by the Division of Comparative Medicine (DCM). As a scientist using aquatic model organisms to address fundamental biomedical problems, the possibility of defocusing NIH oversight of comparative medicine research by breaking up NCRR and/or DCM is frightening. If DCM is fractionated it will very likely result in eventual loss of many important animal research resources and aquatic models. Such a move will decrease our national capability to approach future biomedical problems that simply cannot be approached using only the 3 or 4 mammalian systems represented within the portfolios of standing NIH institutes. Historical and current DCM support for aquatic models research is a single critical avenue that has ensured these valuable models continue to develop and offer new insight into biomedical problems.

Recent technical and scientific advancements indicate this is not the time to defocus the NIH commitment to comparative medicine. As you may be aware, newly developed “next generation” sequencing technologies have made it possible for large genomes and complex transcripts to be completely sequenced and assembled in a few weeks at relatively low cost. These pioneering advancements have liberated scientists using aquatic experimental models and placed comparative genomics and transcriptomic analyses at the forefront of international biomedical research efforts. Novel comparative analyses employing a wide array of aquatic experimental models, that a few years ago would have been considered unapproachable, are giving us new knowledge of how organisms and cells adapt to environmental perturbations. Such studies are uncovering alternative strategies that have evolved by each unique organism to sustain life. Thus, next generation sequencing technology is allowing scientists to illuminate complex genetic mechanisms, including those governing difficult to approach life history traits. This is not a time to break up scientific teams and DCM expertise that can best harvest the fruits of our scientific investment.

Comparative medicine as a discrete entity needs to be maintained under singular administrative oversight. Please consider this as you deliberate how best to proceed. The seeds of scientific discovery that fuel the biomedical research enterprise are often produced in alternative experimental models. After 20+ years of interaction with the NIH, I can assure you DCM personnel are some of the best in the entire NIH. Let’s not allow address of other issues to produce the negative result of eventual elimination of DCM, one of the better programs in the NIH.

Sincerely,



Ronald B. Walter, Ph. D.
Professor and University Research Chair in Cancer Genetics
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WAKE FOREST UNIVERSITY
SCHOOL of MEDICINE

WAKE FOREST UNIVERSITY
TRANSLATIONAL SCIENCE INSTITUTE

Department of Pathology
Section on Comparative Medicine
Wake Forest University Primate Center

December 3, 2010

Lyric Jorgenson, Ph.D.
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Office of the Director, NIH
National Institutes of Health
6705 Rockledge Drive, Suite 750
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smrb@mail.nih.gov. (301) 496–6837

Re: The National Institutes of Health (NIH) Scientific Management Review Board (SMRB) meeting of the Translational Medicine and Therapeutics (TMAT) Working Group

To Whom It May Concern:

As one of the nation's oldest programs in comparative medicine, we offer the following statement in support of maintaining both the integrity of the **Division of Comparative Medicine** (DCM, a component of the National Center for Research Resources [NCRR]) and its close affiliation with the Clinical and Translational Science Award (CTSA) consortium. We believe that the DCM has made and continues to make substantial contributions to the NIH effort to improve public health through translational research as instantiated in the CTSA consortium (also a component of the NCRR). The DCM contribution includes its support for research and training in comparative medicine. The academic discipline of comparative medicine – as represented by our program and those at other universities and medical centers – is comprised of veterinary scientists and is based on the premise that suitable animal models can be developed and used to investigate diseases of public health relevance, including the chronic, degenerative, and infectious diseases that comprise the majority of the human health burden. Comparative medicine research is therefore inherently translational because it enables the movement of hypotheses derived from basic science and clinical and epidemiological investigations into animal platforms that can model probable human outcomes. Importantly, the conduct of such research requires both veterinary medical and research training to provide individuals with the knowledge to care for and effectively apply animal models to problems in human health. Through its programs, the DCM supports the development of animal models and insures their availability to the biomedical research community. Equally important, the DCM provides support to train each new generation of veterinary scientists, whose expertise and participation are necessary to facilitate the conduct of translational research.

Our own program in comparative medicine has been in existence since 1957 and has engaged in translational research since that time. Our studies have employed a wide array of animal models that has included pigeons, rabbits, mice, rats, ferrets, pigs, and sheep. Furthermore, nonhuman primates have been at the core of our research programs for almost 50 years. In this regard we were among the first researchers to assess the appropriateness of various Old and New World monkey species for

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investigating the pathogenesis of atherosclerosis. Furthermore, we were the first group to begin large scale investigations evaluating the factors affecting the progression of atherosclerosis and coronary heart disease in female monkeys and, by implication, women. The expertise required to discover these models, to apply them to research problems, and to provide for their humane care was developed with the help of a series of NIH veterinary training and animal support grants. Originally sponsored by the Institute of General Medical Sciences, the support activities for comparative medicine have now been subsumed into the DCM. Included in these activities is our T32 post-DVM research training grant that is now in its 52nd consecutive year of funding. Notably, most of our T32 graduates and those of the other major programs in comparative medicine have gone on to conduct or facilitate research at many of the nation's academic medical centers.

It should also be noted that the DCM has been critical to our continued ability to integrate comparative medicine expertise and activities into the overall translational research effort represented by the CTSA consortium. For example, investigators from our program have used support from the DCM to engage in collaborative investigations with CTSA institutes at eight institutions: the University of Pittsburgh, University of Texas Health Science Center San Antonio, Washington University, Columbia University, Duke University, the University of Pennsylvania, the University of California San Francisco, and Albert Einstein College of Medicine at Yeshiva University. Moreover, the Wake Forest Primate Center – supported in part by funds from the DCM – is one of four asset centers integrated into the Wake Forest University Translational Science Institute. As such, it facilitates translational research in comparative medicine as part of the leadership and operational structure of the Institute.

In summary, the DCM nourishes and sustains academic comparative medicine and the animal models that enable medical advances to move along a translational continuum that ultimately ends with improved patient care and disease prevention. In view of its central role in translational research, we therefore support a strategy that would maintain the integrity of the DCM and its close affiliation with the CTSA consortium. Our recommendation is that the DCM should continue to be linked to the CTSA consortium if that consortium should be moved from the NCRR to a new NIH Institute or Center.

Respectfully,

Thomas B. Clarkson

Thomas B. Clarkson, DVM, DACLAM
Professor of Comparative Medicine

On Behalf of:

The Section on Comparative Medicine (Department of Pathology), the Wake Forest University Primate Center, and the Wake Forest University Translational Science Institute

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