**Association of American Veterinary Medical Colleges**
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**American Veterinary Medical Association**

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February 9, 2011

Drs. Lawrence Tabak and Alan Guttmacher
Co-Chairs, NCRR Task Force
Office of the Director
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892
http://feedback.nih.gov/index.php/ncats/straw-model/

Dear Co-Chairmen Tabak and Guttmacher, and Members of the NIH NCRR Task Force:

As the nation's sole representative for veterinary medical colleges, departments of comparative medicine, and departments of veterinary science, and as the national veterinary professional association representing more than 83% of US veterinarians, the Association of American Veterinary Medical Colleges (AAVMC), and the American Veterinary Medical Association (AVMA), respectfully, write this letter to provide comments and recommendations on the National Center for Research Resources (NCRR) Task Force Straw Model showing the proposed new National Institutes of Health (NIH) homes for current NCRR programs.

We recognize the importance of the NIH's initiative to create the National Center for Advancing Translational Sciences (NCATS), and welcome the potential benefits to our nation's health of an invigorated focus on translational medicine and therapeutics. Our AAVMC member institutions and AVMA member veterinarians are proud of their significant contributions toward improving human health through transdisciplinary involvement and collaboration in translational research and comparative medicine. The support offered by NCRR programs and resources to our veterinary medical educational and research institutions, faculty, and members, have made possible their important contributions to our nation's health, and we greatly appreciate the opportunity to provide comment and recommendations to further advance the successes of critical NCRR programs.

In review of the Straw Model, we have the following comments:

1. To successfully fulfill its mission of accelerating the development and delivery of new, more effective therapeutics, the NCATS will rely on a diversity of appropriately trained laboratory scientists and clinical researchers capitalizing on the development of tools and technologies and making discoveries at molecular and cellular levels that can be tested and proven in animal based studies.

2. Although a logical and rational argument can be made for including NCRR's Clinical and Translational Science Award (CTSA) program, which is designed to develop teams of investigators from various fields of research who can transform scientific discoveries made in the laboratory into treatments and strategies for patients in the clinic, into the new NCATS, the same cannot be said for excluding and dismembering other components of NCRR, such as animal resources, training programs, and high-end instrumentation and technologies which are so critical to NCATS mission.

3. Further, as indicated in the NCRR Task Force Straw Model, proposing to subdivide these other NCRR components disrupts the extant scientific synergies that have been demonstrated meritorious to date, and forfeits the strategic relationships that have been built between programs over the last 20 years. For example, splitting the animal resources into different administrative structures erects a bureaucratic obstacle that needlessly hinders the flow of basic scientific discoveries made in induced genetic mutations in mice to clinically applicable mechanisms-of-action studied and tested in non-human primates.

4. Although it is expected that following this restructuring, NCRR will no longer exist as a center, a rational consideration would be to maintain a large component of NCRR programs together after reassignment of the CTSA program within the new NCATS. Those charged with making these decisions should be mindful that NCRR's unique, cross-cutting programs are and have been successful through careful planning, thoughtful leadership, and effective management by its administrative and scientific staff, program officers, and officials who understand these programs and are most qualified to ensure continued success of their respective programs and initiatives.

We, the AAVMC member institutions, with our specific expertise and engagement in comparative medicine, and the AVMA, which represents all aspects of the veterinary medical profession, therefore strongly recommend that the NCRR's Division of Comparative Medicine (both programs and staff) be retained as a functional entity after reassignment of the CTSA program. The optimal location of the unit within the NIH (e.g., NCATS, National Institute of

General Medical Sciences, or Office of the Director), should be carefully deliberated with input from NCRR staff and stakeholders.

The leadership of the AAVMC and AVMA requests the opportunity to meet with the NCRR Task Force to provide comments and informed recommendations on the Straw Model. Please contact either the AAVMC (202-371-9195, ext 115; mpappa@aavmc.org) or the AVMA (800-248-2862, ext 6775; rdehaven@avma.org) at your earliest convenience so that we may make arrangements for such a meeting.

Sincerely,

Marguerite Pappaioanou, DVM, MPVM, PhD, Dip ACVPM
Executive Director
Association of American Veterinary Medical Colleges

W. Ron DeHaven, DVM, MBA
Executive Vice President, CEO
American Veterinary Medical Association

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The Association of American Veterinary Medical Colleges (AAVMC) is a non-profit membership organization working to protect and improve the health and welfare of animals, people and the environment by advancing academic veterinary medicine. Its members include all 33 veterinary medical colleges in the United States and Canada, nine departments of veterinary science, eight departments of comparative medicine, three veterinary medical education institutions, nine international colleges of veterinary medicine, and five affiliate international colleges of veterinary medicine. On the Web: http://www.aavmc.org

The American Veterinary Medical Association (AVMA), established in 1863, is a not-for-profit association representing more than 81,500 veterinarians working in private and corporate practice, government, industry, academia, and uniformed services. Structured to work for its members, the AVMA acts as a collective voice for its membership and for the profession. On the Web: http://www.avma.org

A Recommendation to the NCRR Taskforce from the Academic Primate Centers

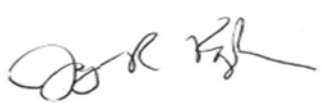
It has been proposed that the National Center for Research Resources (NCRR) be disaggregated, with its various components distributed across the NIH according to the principle of scientific adjacency. The largest single element of the NCRR, the Clinical and Translational Science Award Program, will move to the new National Center for Advancing Translational Sciences. The rationale for this move is the belief that a dedicated translational center will hasten development and application of new therapies and preventive strategies aimed at improving public health. Part of the provisional plan also calls for all programs involving nonhuman primates (the National Primate Research Centers [NPRCs], the Chimpanzee Resource Centers, and the other primate model resources) to be placed in the Director's Office in an 'interim infrastructure unit'. The rest of what was formerly included in the NCRR's Division of Comparative Medicine (DCM) will be assigned to other NIH Centers and Institutes in a manner yet to be decided.

As representatives of some of the nation's most prominent academic primate centers – that is, centers within academic institutions that have extensive research programs using nonhuman primates but are not part of the NPRC program – we strongly believe that fragmentation of the DCM's research, resource, and training programs will be detrimental to the advancement of both translational and discovery research. It is true that the proposed interim infrastructure unit will maintain the contiguity of primate research resources. However, the academic discipline of comparative medicine represented by programs at our institutions and other universities and medical centers is not species specific. Rather, comparative medicine comprises scientists dedicated to the premise that suitable animal models can be discovered, developed, and applied to investigate virtually all diseases of public health relevance. Importantly, comparative medicine research is inherently translational because it enables the movement of hypotheses derived from basic science and clinical and epidemiological investigations into animal platforms that can model human outcomes, elucidate underlying mechanisms of disease, and identify potential therapeutic targets. Not surprisingly, the history of comparative medicine research and its translational contributions reflect a range of model organisms of many types, from non-mammalian species to nonhuman primates.

The programs contained within the currently configured DCM include resource grants that facilitate the development and application of a broad spectrum of animal models, informatics resources that increase the utility of the large genetic and genomic databases required to make systems biology a reality, and research grants that improve animal resources and thereby enhance the ability of the NIH categorical institutes to conduct disease-specific investigations. Additionally, the DCM supports the training grants necessary to educate and provide research experience to each new generation of comparative medicine scientists, whose expertise, participation, and clinical understanding are central to the conduct of translational and basic research using animal models. History demonstrates that DCM programs and activities have enabled the NIH's categorical institutes and centers to take advantage of the full translational continuum of animal models and thereby enhance human health and well-being.

Accordingly, we urge that you maintain within a single administrative home the infrastructure, all animal model resources (including the entire nonhuman primate portfolio), resource-related research, and comparative medicine training activities that are currently within the DCM. We strongly believe that this strategy will help accomplish the NIH leadership's goal to expedite the translation of biomedical

research discoveries into therapeutic and preventive solutions for the diseases threatening public health.



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Director, Wake Forest University Primate Center
Professor of Pathology (Comparative Medicine), Translational Science, and Anthropology
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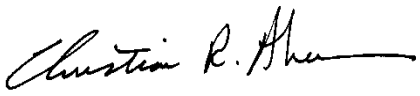

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UNC SCHOOL OF MEDICINE

February 23, 2011

R. Balfour Sartor, M.D.
Midgett Distinguished Professor of Medicine,
Microbiology & Immunology
Director, UNC Multidisciplinary Center
for IBD Research and Treatment
Co-Director, Center for Gastrointestinal
Biology and Disease

Members of Scientific Management Review Board
NIH

Dear Members of the Scientific Management Review Board:

As part of the deliberations regarding the creation of a center for advancing translational medicine and therapeutics development and the fate of the National Center for Research Resources, it is extremely important to consider how to best continue support of the very productive and diverse Animal Resource and Biologic Material Centers that are funded by the NCRR and administered through the NCRR's Division of Comparative Medicine. These approximately 50 centers include the internationally acclaimed National Primate Centers and Mutant Mouse Regional Resource Centers as well as individual highly specialized animal resources such as the National Gnotobiotic Rodent Resource Center (P40 RR018603) that I direct. These centers provide specialized animals and biologic materials such as antibodies that require very sophisticated technical expertise and are very labor intensive. Therefore, they are beyond the technical and financial capabilities of individual NIH supported investigators. However, these resources are essential for mechanistically oriented research in animal models that help develop new therapeutic agents to treat human diseases. These animal resources are used by investigators around the world. For example, in the 2009-10 funding cycle our relatively small National Gnotobiotic Rodent Resource Center with annual direct costs of $360,899 has supplied germ-free (sterile) and selectively colonized mice and rats to 43 individual principal investigators in 20 universities and the NIAID intramural program and trained personnel from 3 universities and the NAIAD intramural program in gnotobiotic techniques so they could start their own small germ-free mouse colonies with our continued support and direction. In the initial 4 years of funding of our center, we provided gnotobiotic rodents to 61 investigators in 35 institutions and our user base has progressively grown. In that time frame, 39 currently funded and 11 pending grants depend on our National Gnotobiotic Rodent Resource Center as a source of gnotobiotic animals to complete these aims. The Zebrafish International Resource Center distributes 110,000 fish to 700 scientific users each year. The animal-oriented Comparative Medicine Division within NCRR understands the needs of both the producers and users of these important resources and has done an excellent job of expanding and optimizing

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these resources in a cost effective manner. Leadership of the Comparative Medicine Division have a veterinary background and can easily communicate with the principal investigator and staff of each funded facility. This background is quite different from the typical biologic science background of most NIH grants administrators. The NCRR program managers have a very hands on approach and are valuable allies in developing optimal animal resources for the broad group of NIH funded investigators while conserving expenses and maximizing efficiencies. The annual meeting of the principal investigators of the animal resource units funded by the NCRR and the Division of Comparative Medicine staff has been a very productive way of sharing experiences and communicating new ways of developing animal models of human disease in a very cost effective manner.

I strongly encourage continuing this important division, regardless of what institutional structure is decided upon. It is essential to have an experienced NIH grants administrative team that can effectively communicate with principal investigators to optimize resources while conserving costs. The entire community of investigators supported by the NIH profits immensely by the small investment in centralized animal resources that are very effectively administered by the NCRR Comparative Medicine Division staff.

Sincerely,

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Co-Director, Center for Gastrointestinal Biology and Disease
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17 February 2011

Drs. Lawrence Tabak and Alan Guttmacher
Co-Chairs, NCRR Task Force
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National Institutes of Health
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smrb@mail.nih.gov

Dear Co-Chairs Tabak and Guttmacher, and Members of the NIH NCRR Task Force:

The School of Veterinary Medicine at the University of Wisconsin writes this letter to provide comments and recommendations on the National Center for Research Resources (NCRR) Task Force Straw Model showing the proposed new National Institutes of Health (NIH) homes for current NCRR programs.

The support offered by NCRR programs and resources to our institution and faculty have been instrumental in training the next generation of veterinary clinician researchers. Currently we have two training grants through the NCRR Division of Comparative Medicine. One of these (T32; PI: Bjorling) supports veterinary students who choose to take a year out of their professional curriculum to do research. The other training grant (T32; PI: Czuprynski) supports DVMs who wish to pursue advanced research training (PhD). Furthermore, we have recently submitted a proposal to NCRR (T35; PI: Behan) to support veterinary students who wish to spend a Summer doing research during their professional curriculum. Together these programs broaden the pipeline of potential clinician scientists. We have also received support from the NCRR to hold a Clinician Scientist Training Workshop to provide entry level training in applied research skills to veterinary clinicians (R13; PI: Trepanier). In addition to these grants to faculty in the School of Veterinary Medicine, we have several veterinary clinician researchers supported through the CTSA at the University of Wisconsin-Madison (PI: Drezner).

With respect to the Straw Model, we have the following comments:

1. It is not clear where these important research training opportunities for veterinary students and graduate veterinarians (T32, T35, R13) will reside in a restructured NCRR.

2. Programs supported by the Division of Comparative Medicine have been tremendously successful due to the thoughtful leadership and effective management of the scientific staff and program officers in the Division. They understand our needs and know how to make these programs a success. It seems logical that this group of programs would be combined with the CTSAs in the new NCATS.

We therefore strongly recommend that the NCRR's Division of Comparative Medicine (both programs and staff) be retained as a functional entity after reassignment of the CTSA program. The optimal location of the unit within the NIH should be carefully deliberated with input from NCRR staff and stakeholders.

Please do not hesitate to contact us if we may provide additional information regarding our recommendations on the Straw Model.

Sincerely,

Mary Behan, PhD
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February 22, 2011

Dear Members of the SMRB:

As you may recall, at the December 7, 2010 meeting of the SMRB, I was the only member who voted against the proposal recommending creation of the National Center for Advancing Translational Sciences (NCATS). I did so because the implications of creating the new Center on all of NIH had not been adequately considered. In particular, I was concerned that creating NCATS would substantially impact the National Center for Research Resources (NCRR), as was implicitly clear from the meeting agenda, presentations, and public comments. The passed motion stated in part that "the SMRB endorses and supports the NIH commitment to undertake a more extensive and detailed analysis through a transparent process to evaluate the impact of the new Center on other relevant extant programs at NIH, including NCRR…". However, as I feared, this process has been short-circuited.

The process was initiated immediately after the meeting with the creation of an NCRR task force and the launching of a new feedback website. This site rapidly received many comments regarding the potential negative impacts on NCRR programs. However, prior to integrating either these comments or additional input from conference calls with NCRR stakeholders and prior to reporting to the SMRB, the NIH Director recommended to the Secretary of Health and Human Services that NCRR be abolished, and she, in turn, informed Congress of her determination on January 14th, 2011. Although the Secretary does have the legal authority to abolish a Center without involving the SMRB, this approach violates the spirit of the creation of the SMRB, namely, "to advise the NIH Director and other appropriate agency officials, through reports to the NIH Director, on the use of these organizational authorities and identify the reasons underlying the recommendations."

Given that this will be the first time an institute or center at the NIH has been abolished and the first time the SMRB process has been used to create a new center, the SMRB role here is more critical than at any other juncture. The precedent you are setting will be historic. **I strongly urge the SMRB to recommend to the NIH Director, to the Secretary of Health and Human Services, and to Congress that NCRR not be abolished at this time, pending an appropriately transparent process, following the principles outlined in the SMRB report, *Deliberating Organizational Change and Effectiveness*.** On the following pages, I summarize the basis for my vote last December and for my recommendation to you now. I have heard from many in the scientific community who share my view.

Respectfully,

*Jeremy M. Berg*

Jeremy M. Berg
Director, National Institute of General Medical Sciences
National Institutes of Health

**NIH Organizational Change Process: December 2010-February 2011**

In the days leading up to the SMRB meeting on December 7th, I became very concerned that the decision to recommend creation of NCATS would be followed by a recommendation to abolish NCRR without appropriate discussion. I was particularly concerned that the decision to break up an NIH Institute or Center should follow at least the spirit, if not the letter, of the SMRB process described in *Deliberating Organizational Change and Effectiveness*. I e-mailed the SMRB Chair on December 4th expressing these concerns (see Appendix) but did not receive a response. Instead, the Office of the Director contacted me on December 5th, not to discuss the substance of my concerns, but rather to urge me not to pursue this approach. After several hours of consideration, I shared my e-mail with a number of Institute Directors, some of whom indicated privately that they shared a number of the same concerns.

At the December 7th meeting, presentations were made by the TMAT working group and the Director of NCRR, among others. In addition, a number of public comments were presented expressing concern about the fate of NCRR and its programs as well as the haste with which the reorganizational process was moving. When the motion to recommend the creation of a transitional center was put forth, I asked "Did the TMAT Working Group consider a model in which the TMAT-related resources were placed in an existing IC, such as NCRR, with additional restructuring, including, perhaps, recruitment of new leadership as an option?" The brief answers given by two Working Group members indicated that this alternative was not examined in any detail. There was no additional discussion, and the SMRB voted 12-1 in favor of the motion. The lack of serious consideration of this possible alternative appeared to me to be a significant flaw in the process.

In December, the NIH Director did initially suggest NCRR might not be abolished. However, within less than two weeks, it appears that Dr. Collins had notified the Secretary of his recommendation that NCRR be abolished. It has not been disclosed what was responsible for this decision.

NIH launched a feedback website to solicit comments regarding organizational changes related to the creation of NCATS. By January 13th, more than 1,100 comments had been submitted, most expressing support for NCRR programs and concerns about their fate.

Nonetheless, the Secretary of Health and Human Services sent letters to Congress on January 14th stating that:

> "I have…determined that the National Center for Research Resources (NCRR) is no longer required …."

On January 16th, a "straw model" outlined the proposed redistribution of NCRR programs. Only the CTSA program would go to NCATS. A few other programs

would move to NIGMS, NIBIB, and NIMHD. The majority of NCRR programs would be assigned to a new entity, the "Interim Infrastructure Unit". Since then, more than 150 comments have been posted on this model, many of which express strong support for one or more NCRR programs and their interrelatedness, and some of which raise significant concerns about various aspects of the proposed reorganization.

We are left to wonder on what basis was it determined that NCRR is no longer required. Since the SMRB did not address this key question, and no transparent process was pursued prior to this decision, the rationale must be gleaned from comments released to the media.

**Is it related to the quality and necessity of NCRR programs?**

Apparently not; many, including the NIH Director (Nature), have expressed strong support for these programs.

Indeed, the proposed creation of an "Interim Infrastructure Unit" in the "straw model" suggests that some parts of NCRR do need to function as a freestanding unit apart from any existing institute or center. Furthermore, it has been suggested that this "Infrastructure Unit" may not be interim (Science).

**Is it related to the limitation of the number of Institutes and Centers?**

There has been considerable confusion about this point, but the NIH Director indicated that this "has not been a factor in (his) thinking" (Science).

**Is it related to the transfer of the CTSA program out of NCRR?**

The NIH Director has raised the concern that NCRR without the CTSA program would be too small to make sense (Science).

However, even without the CTSA program, NCRR would rank in size 12$^{th}$ of out 24 institutes and centers, larger than NIEHS, NIAMS, NHGRI, NIDCD, NIDCR, NIAAA, NLM, NIBIB, NIMHD, NINR, NCCAM, and FIC.

**Are there potential benefits to distributing NCRR programs across NIH?**

There has been considerable discussion of the benefits of "new adjacencies" for some NCRR programs. Of course, the creation of these new adjacencies requires the loss of existing adjacencies within NCRR, the perceived value of which has been one of the strongest themes emerging from the public comments. The issue of adjacencies gained and lost is crucial and is exactly the sort of issue that should have been addressed by a full public process where a range of stakeholders could present their perspectives ***prior*** to any decision to abolish NCRR.

I understand that the model developed by the NCRR task force will be presented to the SMRB at the February 23 meeting and that numerous changes from the "straw model" have been made. The task force has worked diligently to obtain input from a wide range of stakeholders. This, however, has been done under time constraints that are much too tight to allow for optimal results.

As a specific example of how hasty the process has been, consider the NCRR IDeA (Institutional Development Award) program, originally assigned to the Interim Infrastructure Unit in the "straw model". At approximately 5:30 P.M. on February 8th, one of the NCRR task force co-chairs called me to discuss having the IDeA program moving to NIGMS. As far as I am aware, there had been no previous discussion of NIGMS taking the IDeA program raised publicly at NIH or at the stakeholder meetings. During this telephone conversation, it was proposed that NIGMS take the IDeA program in lieu of the non-primate model organism resources program, which would instead be kept with other components of the Comparative Medicine Division in the Interim Infrastructure Unit. I was initially asked to provide an answer the next day (February 9th) before 9:30 A.M. but was given an extension until later that afternoon.

Thus, I was given *approximately 24 hours* to decide whether NIGMS should take on a large (>$200M), complicated program not closely related to our core mission. Because I supported keeping the Comparative Medicine Division programs together, I indicated hesitant approval for moving the IDeA program to NIGMS in the new model. I did so, however, with very little comfort that this was a sound decision since I had not had anywhere near an appropriate period of time to familiarize myself with anything other than the rudiments of the program, to consult with NIGMS staff, or to meet with the staff from NCRR who direct the IDeA program.

The rushed decision to assign this program to NIGMS is particularly troubling to me, as Director of NIGMS, since statements have been made (Science) that other programs assigned to the "Interim Infrastructure Unit" might ultimately be transferred to NIGMS. NIGMS does have a long history of productive interactions with NCRR, although the two units have substantially different missions. Any decisions to move NCRR programs to NIGMS should be made only after careful consideration of the impact of such a transfer both on the programs themselves and on NIGMS.

**What is the rationale for approaching this potential reorganization in a hurried manner?** Certainly, many in the scientific community, in both the public and private sectors, are greatly concerned about the challenges of translating basic science knowledge to improve human health and, more specifically, about the number of new drugs reaching the American public. However, acting to address this important issue does not require a rush to create a new

organizational structure in fiscal year 2012, especially if this requires moving forward on other reorganizations for which there is insufficient time for appropriate discussion. Indeed, many of the programs that will potentially move to form NCATS already exist and have been operating for a number of years with support from the NIH Common Fund and the NIH institutes and centers. Furthermore, several options are certainly available for creating NCATS without abolishing NCRR. The input that has come into NIH since the December 7th SMRB meeting has only served to emphasize how important and well-integrated the infrastructure, resource, and capacity-building programs of NCRR are to the scientific community, to NIH, and, indeed, to the challenge of translating basic discoveries into improvements in human health. The SMRB should fulfill its responsibility to provide a transparent forum to discuss the potential costs and benefits of abolishing NCRR before any decision is finalized.

(Appendix: December 4th -e-mail to SMRB Chair)

From: Berg, Jeremy (NIH/NIGMS) [E]
Sent: Saturday, December 04, 2010 2:54 PM
To: Augustine, Norman
Cc: Patterson, Amy (NIH/OD) [E]
Subject: The formation of the translational science center and NCRR

Dear Norm:

I am writing regarding our upcoming discussion of the possible formation of a new translational research center. The working group has examined the merits of forming such as center and possible structural models one. However, they appear not to have examined extensively the possible implications of dissolving the National Center for Research Resources (NCRR) to make room for such a center. I am struck by the letter sent to you and Dr. Collins from the members of the National Advisory Research Resources Council (NARRC) in which they raise concerns about the lack of deliberations regarding the potential impact of reorganization on the programs supported by NCRR as well as several of the other public comments. I wanted to let you know that I share their concerns.

In my opinion, if the SMRB were to endorse a decision to dissolve NCRR to make room for the new translational center without much more extensive internal discussions and input from stakeholders, we run a substantial risk of significantly harming the reputation of the SMRB. The SMRB was established as a deliberative body to support an open and relatively comprehensive analysis of any major organizational changes at NIH. The fact that the NARRC and other key stakeholders just learned recently of the possibility that formation of the new translational center would require distributing most of the non-CTSA programs within NCRR has not allowed for this open discussion. These concerns are also clear from other components of the scientific community (see some of the other letters as well as http://news.sciencemag.org/scienceinsider/2010/12/creating-one-nih-center-might.html?ref=hp ). Note that the non-CTSA components of NCRR are, in aggregate, larger than all of NIAAA, the fate of which we discussed extensively over quite some time.

Some of the key questions that come to mind are:

(1) Should NCRR be dissolved at all or should the formation of the new translational center wait for the creation of a space by the completion of the formation of the new substance use, abuse, and addiction institute?

(2) If NCRR is dissolved should the various programs be kept together as much as possible or should each program be moved to its most natural home within another institute or center?

(3) What are the implications of the dissolution of NCRR on the institutes and centers that would adopt these programs?

(4) What are the implications of the dissolution of NCRR on the institutes and centers that interact with or depend on NCRR programs?

I hope we have a frank discussion of these issues at our meeting.

Respectfully, Jeremy

Jeremy M. Berg
Director, National Institute of General Medical Sciences

Full disclosure:(1) It will be announced Monday that I will be stepping down as NIGMS Director in June, 2011. This is primarily due to opportunities for my wife's career and not to issues related to my position at NIH.

(2) NIGMS is one of the institutes that is likely to adopt a significant number of programs from NCRR.

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February 22, 2011

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**RE: AAMC Public Comments to the NCRR Task Force and Scientific Management Review Board for the SMRB Meeting on Feb. 23**

Dear Drs. Tabak and Guttmacher:

On behalf of the Association of American Medical Colleges (AAMC), I write with further comments on the proposed reorganization of research resource programs currently within the National Center for Research Resources (NCRR). Please consider these comments as an addendum to the AAMC's statement submitted to the NIH Scientific Management Review Board on December 7. At that time, the AAMC urged the NIH to support a broad focus for any new center and to support investigation across the continuum of translational science (including community-based participatory research). The AAMC also urged the NIH to gauge the impact of any reorganization on the important infrastructure and resource programs currently managed by NCRR, including soliciting input from all affected research communities. The Association is grateful that the NIH's statements and actions to date are consistent with what the AAMC and other organizations asked for at that time, especially with establishment of your Task Force, the opportunities granted for public feedback, and the respect for transparency shown in this process.

In agreement with much of the biomedical research community, which has commented on the proposed "straw model" for reorganization, the AAMC again would like to emphasize the importance of NCRR's component programs, including but not limited to Comparative Medicine, Biotechnology Centers, the Biomedical Informatics Research Networks, Shared Instrumentation, Research Centers at Minority Institutions, and the Institutional Development Awards Program. These programs have been effective, even indispensible, in serving the NIH mission. The AAMC appreciates that an express goal of the Task Force is to consider other synergies (or "adjacencies") that could be created or enhanced by relocating these programs. The

straw model demonstrates that the NCRR working group is carefully considering how these new adjacencies may be created, and we believe the research communities affected by these programs are in the best position to consider the relative advantages of collocating programs within other institutes or centers.

The AAMC has a separate concern from the organizational questions in the proposed straw model. Wherever programs are eventually located, we urge the Task Force and the SMRB to consider how best to protect the effectiveness, integrity, and continuation of these programs, including their budget planning and operational support. It remains unclear how these programs will be operationally incorporated into other ICs, which are planning for their existing portfolios, in a way that ensures continuation and support for these resource programs. This process is complicated because of the uncertainties surrounding the current fiscal year, the necessity to amend the FY 2012 budget to reflect the reorganization, and the need to begin planning for FY 2013. There is of course risk that NCRR programs relocated to other ICs will be disadvantaged in the resulting budget process, particularly as NIH resources overall become more constrained. Conversely, the AAMC does not believe that any programs should receive, nor that NIH leadership could grant "guaranteed" levels of support for these or any other resource programs. Again, clarification or guidance for how IC management should achieve the necessary balance to address such concerns is needed.

The AAMC therefore makes the following recommendations:

1. The Task Force should explicitly address how best to minimize disruption of the functional integrity of the programs, including budget and program planning processes, and also maintain staff expertise in program planning, budgeting and other central functions that currently reside within the NCRR. This recommendation would also apply to those programs that may be temporarily moved to the Office of the Director and administered by the Division for Program Coordination, Planning, and Strategic Initiatives (DPCPSI).

2. NCRR programs currently benefit from direction of an advisory council comprised of members who understand these resource and infrastructure programs. The AAMC believes that new members with experience in these resource programs should be integrated within the advisory councils of the ICs to which the programs are transferred.

3. The straw model should make explicit mention of the *training* programs currently conducted within NCRR, including within the CTSAs and other programs. Given the special status and concern for research training, the model should make clear which programs will continue within the National Center for Advancing Translational Sciences and which will move to other ICs.

4. Finally, we urge the NIH to establish a formal evaluation process within the SMRB or other appropriate entity to determine how effectively NCRR resource programs are operating within their new homes. Such evaluation should begin six to twelve months after the transfer, in time to catch disruption in the programs' review and award cycle.

The AAMC again is grateful for the continued opportunity to comment on and work with the NIH on these proposals, and we look forward to discussion of these and other points.

Sincerely,

Ann Bonham, Ph.D.
Chief Scientific Officer

FasterCures
The Center for Accelerating Medical Solutions

# Public Comments Submitted to the National Institutes of Health Scientific Management Review Board

*Adam M. Clark, Ph.D.*
*Director, Scientific and Federal Affairs*
*FasterCures/The Center for Accelerating Medical Solutions*

February 23, 2011

*FasterCures* is a non-profit, non-partisan center dedicated to accelerating the progress of discovery and development of new medical solutions for deadly and debilitating diseases. As part of our mission we work across the disease spectrum with all the sectors in the medical system to improve the effectiveness and efficiency of biomedical research.

We applaud the Board's recommendations to create the National Center for Advancing Translational Sciences (NCATS) which expands NIH's investments in efforts to speed the translation of basic discoveries to clinical application. We view this as a significant development for the future of getting basic discoveries translated into much needed and long awaited treatments and cures.

NCATS has the potential to cut across institutional boundaries and address fundamental scientific and biomedical challenges regardless of disease type. This integration of efforts will produce synergy that will benefit Americans through improved health and more efficient and effective investment of their tax dollars.

The transition from basic research to clinical application requires interdisciplinary and multidisciplinary expertise. As we had outlined in a *FasterCures* whitepaper "Crossing Over the Valley of Death," many new drugs drop out of the development pipeline for a variety of reasons including lack of funding for critical translational studies and insufficient investment in the technical expertise needed for technology development and transfer. These barriers stand in the way of both the scientists dedicated to improving health and the patients who ultimately need improved cures and care.

We need to bridge the void between basic discoveries and better medicine. The steps in between discovery and application, like target validation, assay qualification, product refinement, and pre-clinical development are necessary investments to move promising new interventions to the patient. These areas of focus are often the bottleneck to moving drugs forward and exist across the drug development enterprise regardless of the disease.

We believe that NIH's proposed new center will provide a significant stimulus to moving ideas out of the lab and into the clinic and we fully support NIH's willingness to disrupt its own paradigm in search of better solutions.

Colorado State University

21 February, 2011

College of Veterinary Medicine
and Biomedical Sciences
Office of the Dean
1601 Campus Delivery
Fort Collins, Colorado 80523-1601
(970) 491-7051
Fax: (970) 491-2250
www.cvmbs.colostate.edu

Drs. Lawrence Tabak and Alan Guttmacher
Co-Chairs, NCRR Task Force
Office of the Director
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892
smrb@mail.nih.gov

Dear Co-Chairs Tabak and Guttmacher, and Members of the NIH NCRR Task Force:

The College of Veterinary Medicine and Biomedical Sciences at Colorado State University writes this letter to provide comments and recommendations on the National Center for Research Resources (NCRR) Task Force Straw Model showing the proposed new National Institutes of Health (NIH) homes for current NCRR programs.

We recognize the importance of the NIH's initiative to create the National Center for Advancing Translational Sciences (NCATS), and welcome the potential benefits to our nation's health of an invigorated focus on translational medicine and therapeutics. Our College's faculty members are proud of their significant contributions toward improving human health through transdisciplinary involvement and collaboration in translational research and comparative medicine. The support offered by NCRR programs and resources [in the past 10 years, these include partial funding for: 1) our Biohazards Research Building, a biosafety level 3 facility for infectious disease research, 2) the Animal Cancer Center, 3) addition to and upgrading the Painter Center (our campus's primary facility for housing small research animals), 4) the Regional Biocontainment Laboratory, and 5) T32 training programs and K series young investigator awards to produce our future biomedical scientists] to our institution and faculty have made possible their important contributions to our nation's health, and we greatly appreciate the opportunity to provide comment and recommendations to further advance the successes of critical NCRR programs.

In review of the Straw Model, we have the following comments:

1. To successfully fulfill its mission of accelerating the development and delivery of new, more effective therapeutics, the NCATS will rely on a diversity of appropriately trained laboratory scientists and clinical researchers capitalizing on the development of tools and technologies and making discoveries at molecular and cellular levels that can be tested and proven in animal based studies.

2. Although a logical and rational argument can be made for including NCRR's Clinical and Translational Science Award (CTSA) program, which is designed to develop teams of investigators from various fields of research who can transform scientific discoveries made in the laboratory into treatments and strategies for patients in the

clinic, into the new NCATS, the same cannot be said for excluding and dismembering other components of NCRR, such as animal resources, training programs, and high-end instrumentation and technologies which are so critical to NCATS mission.

3. Further, as indicated in the NCRR Task Force Straw Model, proposing to subdivide these other NCRR components disrupts the extant scientific synergies that have been demonstrated meritorious to date, and forfeits the strategic relationships that have been built between programs over the last 20 years. For example, splitting the animal resources into different administrative structures erects a bureaucratic obstacle that needlessly hinders the flow of basic scientific discoveries to clinically applicable mechanisms-of-action studied in rodents, non-human primates and other relevant animal model systems.

4. Although it is expected that following this restructuring, NCRR will no longer exist as a center, a rational consideration would be to maintain a large component of NCRR programs together after reassignment of the CTSA program within the new NCATS. Those charged with making these decisions should be mindful that NCRR's unique, cross-cutting programs are and have been successful through careful planning, thoughtful leadership, and effective management by its administrative and scientific staff, program officers, and officials who understand these programs and are most qualified to ensure continued success of their respective programs and initiatives.

We therefore strongly recommend that the NCRR's Division of Comparative Medicine (both programs and staff) be retained as a functional entity after reassignment of the CTSA program. The optimal location of the unit within the NIH (e.g., NCATS, National Institute of General Medical Sciences, or Office of the Director), should be carefully deliberated with input from NCRR staff and stakeholders.

Please do not hesitate to contact us at (970) 491-7053 (email: terry.nett@colostate.edu or sue.vandewoude@colostate.edu ) if we may provide additional information regarding our recommendations on the Straw Model.

Sincerely,

Terry Nett

Terry Nett, PhD
Associate Dean for Research
& Graduate Education

Sue VandeWoude

Sue VandeWoude, DVM, PhD
Incoming Associate Dean for Research
& Graduate Education

| | |
|---|---|
| **From:** | Borries Demeler |
| **To:** | SMRB (NIH\OD) |
| **Subject:** | NIH SMRB DEADLINE: Feb. 22 for Public Comments |
| **Date:** | Sunday, February 13, 2011 12:40:08 PM |

Dear Dr. Jorgensen,

I would like to submit a written comment for the next SMRB teleconference about the reorganization of NCRR and the proposed new center for advancing translational medicine and therapeutics development. My name, address, telephone number and professional affiliation is listed in my signature line.

I am greatly concerned that the proposed restructuring of the NCRR will lead to a diminishing funding focus on instrument development and basic research, will lead to a reduction in technological advances, and will end up being used as a backdoor for implementing budget cuts. I am certain that such shifts of focus would negatively affect cutting-edge research efforts supported by a variety of other NIH institutes. As a recipient of RO1 funding for method and software development for biophysical instrumentation, NCRR's support of our efforts in turn supports a large number of NIH-funded investigators in a wide range of fields, who have made significant discoveries by using the cutting-edge instrument and software developments resulting from the NCRR supported RO1 grants we and others depend on for generating leading technological advances. I am skeptical about the wisdom of separating P41 centers from a central NCRR administration and distributing them among different institutes. This could lead to a change of emphasis where future homes of P41 center grants will serve mostly the institutes under which they are administered (e.g., NIBIB, NIGMS), instead of the interests of a broader audience from many different NIH institutes. Also questionable is whether such reorganization will maintain/expand funding levels for P41s. I feel that a separate institutional entity such as the NCRR is critical to keep the focus on instrument development, basic research, and P41 centers, even though the translational effect of such efforts may not be immediately obvious but instead manifests itself indirectly through the impact these efforts have on translational research elsewhere.

Thank you, -Borries Demeler
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Borries Demeler, Ph.D.
Associate Professor
The University of Texas Health Science Center at San Antonio
Dept. of Biochemistry, MC 7760
7703 Floyd Curl Drive, San Antonio, Texas 78229-3901
Voice: 210-767-3332, Fax: 210-567-1136, Email: demeler@biochem.uthscsa.edu

**From:** Hugh Fan
**To:** SMRB (NIH\OD)
**Subject:** SMRB Public Comment
**Date:** Thursday, February 17, 2011 11:27:03 AM

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Dear Scientific Management Review Board,
I am a current grantee of National Center for Research Resources (NCRR) and worried about the impact of the proposed dissolution of NCRR. I participated in one teleconference organized by Dr. Tabak on Jan. 20, 2011. I appreciate their efforts and understand the reasons for establishing National Center for Advancing Translational Sciences (NCATS), but the reasons for dismantling NCRR in order to have NCATS is not very convincing. Why does not NIH simply establish NCATS without dismantling NCRR while the law does not limit NIH to 27 institutes and centers? Alternatively, why does not NIH simply expand CTSA (Clinical and Translational Science Award) program within NCRR?

In the "NCRR Program Summaries" document, many NCRR programs are vital to NIH and the research communities. For example, "The R21 Instrumentation Development program ($11.8 M) is unique at NIH, providing support specifically for new or improved instrumentation for biomedical research." Under the proposed arrangement, the most of these programs will become a part of "interim infrastructure unit", which will last for about one year (per teleconference conversation). How realistic is it for NIH to find the permanent home of each program within one year? If these programs are very compatible with other institutes/centers, they were unlikely placed in NCRR at the first place. If finding a permanent home lasts longer, what are the impacts of the "interim" status on the existing awards, program managers/stuffs, and more importantly, future awards?

In the interview with *Science*, Dr. Collins (NIH director) said that NIH could not discuss publicly the possible dismantling of NCRR before informing the congress, but why could NIH publicly discuss the formation of the new translational center?

Thank you for the opportunity to express my concerns.
Best regards,
Hugh
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Hugh Fan, Ph.D.
University of Florida
PO Box 116250
Gainesville, FL 32611
Tel: 352-846-3021
Email: hfan@ufl.edu
Web: www.mae.ufl.edu/~hfan

**From:** Robert Gilmour
**To:** SMRB (NIH\OD)
**Cc:** Ted Mashima; Judy R Wood
**Subject:** SMRB Public Comment
**Date:** Friday, February 18, 2011 2:29:23 PM

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February 18, 2011

Mr. Norman Augustine

Chair, Scientific Management Review Board

Office of the Director

National Institutes of Health

6705 Rockledge Drive, Suite 750

Bethesda, MD 20892

smrb@mail.nih.gov

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

I am writing on behalf of Cornell University's College of Veterinary Medicine to provide comments and recommendations on the National Center for Research Resources (NCRR) Task Force Straw Model.

We recognize the importance of the NIH's initiative to create the National Center for Advancing Translational Sciences (NCATS) and appreciate the potential benefits to our nation's health of an invigorated focus on translational medicine and therapeutics. Faculty in our College continue to be fully committed to making scientific contributions toward improving human health by participating in collaborative translational research and sharing their expertise in comparative medicine. The financial support and organizational efforts provided by NCRR programs and resources to our institution have advanced science, fostered the career development of junior scientists, and provided an infrastructure for comparative medicine biomedical research. The opportunity to provide comment and recommendations to further advance the successes of critical NCRR programs is welcome.

It is unfortunate in our view that consideration of the disposition of the elements of NCRR other than the CTSAs is occurring on a *post-hoc* basis. The cross-cutting programs encompassed by NCRR are and have been successful through careful planning, thoughtful leadership, and effective management by its administrative and scientific staff, program officers, and officials who understand these programs and are most qualified to ensure continued success of their respective programs and initiatives. Consequently, we believe equally careful consideration should be given to

the reorganization of these programs and that every effort should be made to maintain their cohesiveness in future iterations of the Center.

With respect to specific elements of the Straw Model:

1. To successfully fulfill its mission of accelerating the development and delivery of new, more effective therapeutics, the NCATS will rely on a diversity of appropriately trained laboratory scientists and clinical researchers capitalizing on the development of tools and technologies and making discoveries at molecular and cellular levels that can be tested and proven in animal based studies. The training of a large segment of these individuals has been a focal point of NCRR programs in the past, in particular the diverse array of training grants.

2. Although a logical and rational argument can be made for including NCRR's Clinical and Translational Science Award (CTSA) program, the same cannot be said for excluding and dismembering other components of NCRR, such as animal resources, training programs, and high-end instrumentation and technologies that are so critical to NCATS mission.

3. Further, as indicated in the NCRR Task Force Straw Model, proposing to subdivide these other NCRR components disrupts the extant scientific synergies that have been effective to date, and forfeits the strategic relationships that have been built between programs over the last 20 years. For example, splitting the animal resources into different administrative structures erects a bureaucratic obstacle that needlessly hinders the flow of basic scientific discoveries made in induced genetic mutations in mice to clinically applicable mechanisms-of-action studied and tested in non-human primates.

4. Although it is expected that following this restructuring, NCRR will no longer exist as a center, a rational consideration would be to maintain a large component of NCRR programs together after reassignment of the CTSA program within the new NCATS.

For the reasons given above, it is strongly recommended that the NCRR's Division of Comparative Medicine (both programs and staff) be retained as a functional entity after reassignment of the CTSA program.

Please do not hesitate to contact me at 607-253-3755 or by email at rfg2@cornell.edu if you would like additional information or input.

Sincerely,

Robert F. Gilmour Jr.

Associate Dean for Research and Graduate Education

Professor of Physiology

Cornell University College of Veterinary Medicine

| | |
|---|---|
| **From:** | Michelle Kienholz |
| **To:** | SMRB (NIH\OD) |
| **Subject:** | Feb 23 SMRB Meeting |
| **Date:** | Sunday, February 13, 2011 2:39:37 PM |

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Greetings –

I am writing to express my concern regarding the scheduled allotment of just two hours to the upcoming SMRB meeting, announced in the Federal Register but not, as yet, on the SMRB Website, given the volume and importance of material to be discussed.

Page 21 of the Report on Translational Medicine and Therapeutics notes that as part of the motion approved at the December 7, 2010 SMRB meeting:

- The Board endorse and support the NIH's commitment to undertake a more extensive and detailed analysis through a transparent process to evaluate the impact of the new center on other relevant extant programs at NIH, including NCRR; and

- The NIH report their findings to the SMRB at its next meeting in approximately three months.

As Dr. Collins emphasized during the December 7th SMRB meeting, the TMAT Working Group was charged to assess only the potential value of a new center focused on translational medicine – not the potential consequences of creating this new entity, even though this went against the SMRB's own stated process as laid out in the Report on Deliberating Organizational Change and Effectiveness.

Other agenda items mentioned in the Federal Register include discussion of the impact of NCATS on NCRR (which I assume would also include the redistribution of NCRR programs) and "next steps regarding future SMRB activities."

I find it rather irresponsible that the SMRB has alloted just two hours to present and deliberate the potential risks and benefits (anticipated and unintended) and overall impact on the rest of the NIH and the extramural research community of not only creating NCATS but also abolishing NCRR (an organizational change that has never been directly or specifically discussed by the SMRB).

Pointed concerns raised in the press, on the NIH Feedback site, by public comment speakers and scribes, by House staffers, and by senior Senators themselves suggest it is not in the interest of the NIH to minimize the priority and import of such deliberation, as is currently intimated by the time allotted on February 23rd and the less than transparent analysis processes to date.

I would certainly hope this meeting represents the first and not the only discussion of these issues and that no organizational changes will be formally implemented until a clear understanding of their consequences and plans to address contingencies (potential pitfalls!) have been demonstrated.

Best regards-

Michelle Kienholz

Michelle Kienholz
University of Pittsburgh
Medical Arts Bldg, 401.6
3708 Fifth Ave
Pittsburgh PA 15213

412-578-9514
mlk39@pitt.edu

| | |
|---|---|
| **From:** | James Mubiru |
| **To:** | SMRB (NIH\OD) |
| **Subject:** | Comments on creation of a new Center for advancing translation medicine and therapeutics |
| **Date:** | Wednesday, February 09, 2011 12:44:27 PM |

Dear Sir/Madam
The NCRR has a couple of training grants in the K-series. These were awarded to junior scientists to fund their research. The scope of these training grants is very wide. How are they going to fit in the new center? The recipients of these grants are worried that they may fall into the cracks and be forgotten.
Thank you very much.
James Mubiru
Texas Biomedical Research Institute
San Antonio, Texas

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

22 February 2011

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

RE: NIH Decision to Eliminate NCRR and to Distribute Programs to Other Institutes and Centers.

Dear Mr. Augustine,

As members of the National Advisory Research Resources Council (NARRC), we are writing once again to express our deep concern about the process by which the Office of the NIH Director has decided to eliminate the National Center for Research Resources (NCRR). We understand and support efforts to strengthen the ability of the NIH to meet its most important goal of improving human health through science but believe that the elimination of the NCRR is not a necessary step toward that goal.

We are specifically troubled that the Scientific Management Review Board (SMRB) did not fully exercise its duties specified in the NIH Reform Act of 2006 *before* the decision to eliminate NCRR was recommended to the Secretary of HHS and then to Congress. The SMRB is charged with making recommendations to the NIH and others on the use of organizational authorities reaffirmed in the NIH Reform Act of 2006 (PL 109-482). It appears to us that the SMRB has not followed its own adopted framework as set forth in Deliberating Organizational Change & Effectiveness (DOCE) for considering and, if warranted, implementing and evaluating organizational change. Decisions to establish or abolish institutes must be preceded by a systematic, transparent process guided by sound criteria and principles and based on the analysis and consideration of multiple sources of information and opinion.

The official charge to the SMRB's Translational Medicine and Therapeutics (TMAT) Working Group did not include any requirement by the SMRB to evaluate the impact creation of the National Center for Advancing Translational Science (NCATS) would have on NCRR and/or the NIH, in general. On December 7, 2010, the SMRB specifically recommended the creation of the NCATS without mention of NCRR's fate yet the formal recommendation to Congress regarding the creation of NCATS also included a recommendation to eliminate NCRR.

The Reform Act expressly provides that with any significant consideration of a proposal for organizational changes, the SMRB must (I) analyze the budgetary and operational consequences of the proposed changes; (II) take into account historical funding and support for research activities at national research institutes and centers that have been established recently relative to national research institutes and centers that have been in existence for more than two decades; (III) estimate the level of resources needed to implement the proposed changes; (IV) assuming the proposed changes will be made, make a recommendation for the allocation of the resources of NIH among the national research institutes and national centers; and (V) analyze the consequences for the progress of research in the areas affected by the proposed changes.

The process undertaken over these past months leading to the decision to eliminate NCRR was rushed and excluded members of the affected scientific community, the NCRR leadership, and the NCRR advisory council from any input into the process. Congress and the public expect and deserve, among other things, transparency, stakeholder input, meaningful deliberation and consideration, and

importantly, analysis of impact and consequences *before the fact*, not after decisions have been made. This is essential to ensure continued public trust.

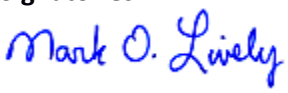
The mission of the NCRR is unique at the NIH, providing flexibility and independence not easily available in categorical ICs. Its programs contribute substantially to ICs that provide extramural funding. The outcry from the research community following announcement of the intention to eliminate NCRR and to reassign its programs to other ICs should be considered in a meaningful way. More than 1100 comments, largely negative, have been registered on the NIH feedback site. Efforts to inform the community *after the fact* by conducting telephone conference calls do not adequately address the concerns raised by the community. The temporary "straw model" pieced together over the Christmas holidays shows the incomplete nature of the planning for reorganization of NCRR programs. Specifically, the creation of the "Interim Infrastructure Unit" as a temporary administrative unit for many of the non-CTSA NCRR programs underscores the difficulty associated with identifying logical new homes for those NCRR programs in other NIH institutes and centers.

We strongly urge the SMRB and Office of the Director to delay any further decisions based on the recommendation to eliminate NCRR and to delay any reassignment of NCRR programs. Proposed changes to existing NCRR programs must involve further open discussion with the scientific community, as well as the other NIH ICs. We see no scientific justification for rushing these decisions in order to complete the reorganization prior to October 1, 2011.

Finally, as we requested in our letter of November 30, 2010, strong consideration should be given to continuation of the NCRR as a free standing center.

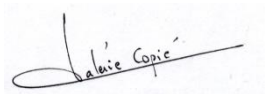
Respectfully submitted, Members of the NARRC,

**Signatories**



**Mark O. Lively, III, Ph.D.**
Professor of Biochemistry
Wake Forest University School of Medicine

**Wendy Chaite, J.D.**
Founder
Lymphatic Research Foundation



**Valérie Copié, Ph.D.**
Associate Professor of Biochemistry
Montana State University

**Mary L. Disis, M.D.**
Director, Center for Translational Medicine in Women's Health
University of Washington

**Emma Fernández-Repollet, Ph.D.**
RCMI Program Director
University of Puerto Rico School of Medicine

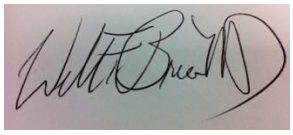
**James E. Heubi, M.D.**
Professor and Associate Chair for Clinical Investigation of Pediatrics
University of Cincinnati College of Medicine

**Dallas M. Hyde, Ph.D.**
Professor of Anatomy
University of California, Davis

**Henry Lewis, III, Pharm.D.**
Dean, College of Pharmacy and Pharmaceutical Sciences
Florida A & M University

**Janet L. Smith, Ph.D.**
Martha L. Ludwig Professor
Department of Biological Chemistry
University of Michigan

**David S. Weir, Ph.D.**
Director, Office of Economic Innovation and Partnerships
University of Delaware



**William F. Bria, II, M.D.**
Chief Medical Information Officer
Shriners Hospitals for Children

**M. Christine Zink, Ph.D., D.V.M.**
Director, Department of Molecular and Comparative Pathology
Johns Hopkins University School of Medicine

**Mark V. Pauly, Ph.D.**
Health Care Systems Department
University of Pennsylvania
Philadelphia, Pennsylvania

CC: Francis S. Collins, MD, PhD, Director, NIH
Larry Tabak, DDS, PhD, Principal Deputy Director
Barbara Alving, MD, Director, NCRR
NARRC Members
SMRB Members

| | |
|---|---|
| **From:** | INFO PEWTRUSTS.ORG |
| **To:** | SMRB (NIH\OD); americanvoices@mail.house.gov; comments@whitehouse.gov; speakerboehner@mail.house.gov; sf.nancy@mail.house.gov; rush.holt@mail.house.gov |
| **Cc:** | info@taxpayer.net; media@cagw.org; info@theteaparty.org |
| **Subject:** | public comment on federal register FW: nih cdc too many billion dollars health agencies doing NOTHING for america |
| **Date:** | Tuesday, February 01, 2011 11:24:16 AM |

THIS AGENCY JUST GREW LIKE TOPSY. AMERICA WANTS SMALLER MORE EFFECTIVE GOVT. THIS IS JUST AN UNWIELDY FAR TOO COSTLY AGENCY. I DO NOT THINK THE INSIDERS WHO DID THE REPORT FOR THE AGENDA GOT IT AND THEY SEEM TO SEILL LIKE THE HUGE BUREAUCRACY IDEA. THE TAXPAYERS DO NOT WANT TO PAY FOR A NEW CENTER FOR "TRANSLATIONAL" MEDICINE. THE BUDGET OF THIS USELESS AGENCY NEEDS TO BE CUT BY A MINIMUM OF 25% IMMEDIATELY AND LAYOFFS NEED TO HAPPEN. AMERICAN TAXPAYERS CANNOT PAY FOR ALL OF THIS FLUFF THAT HAS BEEN GOING ON IN THIS AG4ENCY. CDC AND NIH AND AHRQ AND HRSA ALL NEED TO BE COMBINED INTO ONE EFFECTIVE AGENCY. THE TRILLIONS OF DOLLARS TAXPAYERS HAVE SPENT WITH THIS AGENCY HAVE RESULTED IN AMERICAN HEALTH GOING FROM NO 1 IN THE WORLD TO NUMBER 17. WE ARE NOW ON PAR WITH ROMANIA, A THIRD WORLD COUNTRY. THAT IS HOW OUR BUREAUCRACY WORKS - POORLY. THIS AGENCY HAS DONE A VERY VERY POOR JOB. NOBODY HAS BEEN PAYING ATTENTION  THEY SPEND ALL OF THEI RTRIME TRAVING AROUND THE WORLD GOING TO ALLEGED "CONFERENCES" ALL O NTHE TAXPAYERS WALLET.
JEAN PUBLIC ADDRESS IF REQUIRED

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[Federal Register Volume 76, Number 21 (Tuesday, February 1, 2011)]
[Notices]
[Page 5592]
From the Federal Register Online via the Government Printing Office
[www.gpo.gov]
[FR Doc No: 2011-2190]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Scientific Management Review Board.

The NIH Reform Act of 2006 (Pub. L. 109-482) provides organizational authorities to HHS and NIH officials to: (1) Establish or abolish national research institutes; (2) reorganize the offices within the Office of the Director, NIH including adding, removing, or transferring the functions of such offices or establishing or terminating such offices; and (3) reorganize, divisions, centers, or other administrative units within an NIH national research institute or national center including adding, removing, or transferring the functions of such units, or establishing or terminating such units. The purpose of the Scientific Management Review Board (also referred to as SMRB or Board) is to advise appropriate HHS and NIH officials on the use of these organizational authorities and identify the reasons underlying the recommendations.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Scientific Management Review Board.
Date: February 23, 2011.
Time: 11:30 a.m. to 1:30 p.m.
Agenda: Presentation and discussion will focus on NIH activities related to the Board's recommendations to create a new center for

advancing translational medicine and therapeutics development. As requested by the Board in its Report on Translational Medicine and Therapeutics, NIH will provide an update on the proposed creation of a new center and its evaluation of the impact of such a center on other relevant extant programs at NIH, including the National Center for Research Resources. The Board will also discuss next steps regarding future SMRB activities. Time will be allotted on the agenda for public comment. To sign up for public comment, please submit your name and affiliation to the contact person listed below by February 22, 2011. Sign up will be restricted to one sign up per e-mail. In the event that time does not allow for all those interested to present oral comments, anyone may file written comments using the contact person address below.

The toll-free number to participate in the teleconference is 1-800-779-1545. Indicate to the conference operator that your Participant pass code is ``NIH'.

Place: National Institutes of Health, Office of the Director, NIH, Office of Science Policy, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, (Telephone Conference Call)

Contact Person: Lyric Jorgenson, Office of Science Policy, Office of the Director, NIH, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, smrb@mail.nih.gov, (301) 496-6837.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

The draft meeting agenda, meeting materials, dial-in information, and other information about the SMRB, will be available at http://smrb.od.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: January 25, 2011.
Jennifer S. Spaeth,
Director, Office of Federal Advisory Committee Policy.
[FR Doc. 2011-2190 Filed 1-31-11; 8:45 am]
BILLING CODE 4140-01-P

University of Nebraska Medical Center

NEBRASKA'S HEALTH SCIENCE CENTER

Office of the Vice Chancellor for Research
Comparative Medicine

January 4, 2011

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

Dear Mr. Augustine:

I write to you representing researchers, their staff members and veterinarians who conduct and support research using animal models at the University of Nebraska Medical Center. I would like to comment on the Translational Medicine and Therapeutics (TMAT) working group plans to create a new NIH institute of Translation Medicine and Therapeutics as described in their November 2010 report.

While the formation of this Institute or Center is an opportunity to advance translational and therapeutic medicine, there are some critical specific points that should be considered in order to avoid unnecessary 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 to give strong consideration to and seek expert input from the many comparative medicine veterinary scientists, specialists and research scientists 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.

Sincerely,

FOR: Thomas H. Rosenquist, Ph.D.
Professor and Vice Chancellor for Research

Dr. Francis Collins (francis.collins@mail.nih.gov)
Dr. Arthur Rubenstein (smrb@mail.nih.gov)

985810 Nebraska Medical Center / Omaha, NE 68198-5810402-559-4034 / FAX: 402-559-7927 /
http://www.unmc.edu/dept/Comparativemed/

VirginiaTech
Virginia-Maryland Regional
*College of* Veterinary Medicine

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E-mail:cvmdean@vt.edu
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February 21, 2011

Mr. Norman Augustine
Chair, Scientific Management Review Board
Office of the Director
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892
smrb@mail.nih.gov

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

The Virginia-Maryland Regional College of Veterinary Medicine sends this letter to provide comments on the National Center for Research Resources (NCRR) Task Force Straw Model showing the proposed new National Institutes of Health (NIH) home for current NCRR programs.

Our college recognizes the importance of the NIH's initiative to create the National Center for Advancing Translational Sciences (NCATS), and we welcome the potential benefits of an invigorated focus on translational medicine and therapeutics. Our faculty members are proud of their contributions to improving human health through transdisciplinary involvement and collaboration in translational research and comparative medicine. The support offered by NCRR programs to our institution and faculty have made possible their contributions to our nation's health, and we greatly appreciate the opportunity to provide comments to further advance the successes of critical NCRR programs.

In review of the Straw Model, we have the following comments:

1. To successfully fulfill its mission of accelerating the development and delivery of new, more effective therapeutics, the NCATS will rely on a diversity of appropriately trained laboratory scientists and clinical researchers capitalizing on the development of tools and technologies and making discoveries at molecular and cellular levels that can be tested and proven in animal based studies.

2. Although a rational argument can be made for including NCRR's Clinical and Translational Science Award (CTSA) program, which is designed to develop teams of investigators from various fields of research who can transform scientific discoveries made in the laboratory into treatments and strategies for patients in the clinic into the new NCATS, the same cannot be said for excluding and dismembering other components of

NCRR, such as animal resources, training programs, and high-end instrumentation and technologies which are so critical to NCATS mission.

3. Further, as indicated in the NCRR Task Force Straw Model, proposing to subdivide these NCRR components disrupts the extant scientific synergies that have been demonstrated meritorious to date and forfeits the strategic relationships that have been built between programs over the last 20 years. For example, splitting the animal resources into different administrative structures erects a bureaucratic obstacle that needlessly hinders the flow of basic scientific discoveries made in induced genetic mutations in mice to clinically applicable mechanisms-of-action studied and tested in non-human primates.

4. Although it is expected that, following this restructuring, NCRR will no longer exist as a center, a rational consideration would be to maintain a large component of NCRR programs together after reassignment of the CTSA program within the new NCATS. Those charged with making these decisions should be mindful that NCRR's unique, cross-cutting programs are and have been successful through careful planning, thoughtful leadership, and effective management by its administrative and scientific staff, program officers, and officials who understand these programs and are most qualified to ensure continued success of their respective programs and initiatives.

Our college strongly recommends that the NCRR's Division of Comparative Medicine be retained as a functional entity after reassignment of the CTSA program. The optimal location of the unit within the NIH (e.g., NCATS, National Institute of General Medical Sciences, or Office of the Director) should be carefully deliberated with input from NCRR staff and stakeholders.

Please do not hesitate to contact us at (540) 231-7910 or cvmdean@vt.edu if we may provide additional information regarding our recommendations on the Straw Model.

Sincerely,

Gerhardt G. Schurig, DVM, Ph.D.
Dean

Phillip Scott, Ph.D.
Associate Dean for Research
School of Veterinary Medicine

Professor of Immunology
Department of Pathobiology

Penn Veterinary Medicine

Mr. Norman Augustine
Chair, Scientific Management Review Board
Office of the Director
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892
smrb@mail.nih.gov

February 18, 2011

Dear Mr. Augustine:

The University of Pennsylvania, School of Veterinary Medicine writes this letter to provide comments and recommendations on the National Center for Research Resources (NCRR) Task Force Straw Model showing the proposed new National Institutes of Health (NIH) homes for current NCRR programs. We recognize the importance of the NIH's initiative to create the National Center for Advancing Translational Sciences (NCATS), and welcome the potential benefits to our nation's health of an invigorated focus on translational medicine and therapeutics. However, we are concerned that in creating this center that the important missions of the NCRR might be lost if careful consideration is not given to how the current NCRR programs are maintained.

Penn Vet has a strong interest in the future of the NCRR, since our faculty are heavily oriented towards studying animal disease models to advance biomedical research. Thus, most of our studies are supported by NIH research grants. We have a training program for veterinary scientists and maintain the National Referral Center for domestic animal models of human genetic diseases, both of which are funded from the NCRR. As the breeding stock, tissues, cells and other resources are made available to NIH researchers, we provide an important resource towards meeting the goals of translational medicine. Indeed, the emphasis of this work is on studying diseases that are true homologues of human diseases, as the best approach to developing new treatments.

The support we and others receive from the NCRR have made possible important contributions to our nation's health, and it would be optimal to maintain the institute as an independent entity. However, if that is not possible, we are of the opinion that the most effective use of animal research resources would be to keep the elements of the Division of Comparative Medicine (DCM) together. Furthermore, we advocate merging it into the new

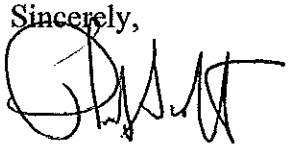
National Center for Advancing Translational Sciences (NCATS). The principal reason is that most of the animal resources supported by DCM are used for translational research, and thus the NCATS would be the most appropriate home for these missions. These resources include the National Primate Research Centers, the Penn Referral Center for Animal Models of Human Genetic Disease, the Missouri National Swine Resource & Research Center, and several rodent resource centers at The Jackson Laboratory and other institutions. The models are used to advance understanding of pathogenesis and as platforms for developing new therapies, including pharmaceuticals, recombinant proteins, organ transplantation, gene therapy, and stem cell approaches. These centers provide animal disease resources to the entire biomedical research community. Keeping DCM within the new NCATS will also help to ensure that the many spontaneous animal diseases similar in pathogenesis and clinical symptomatology to their human counterparts (epilepsy, diabetes, certain cancers, spinal cord injuries, aging disorders) will play their important role in developing new treatments.

The training of veterinarians in biomedical science is also an integral part of the DCM mission. With appropriate scientific training veterinarians bring a valuable perspective of animal physiology and pathology –the twin pillars of medicine – to the scientific research teams and can bridge many practical barriers to conducting translational experiments.

We therefore strongly recommend that if the NCRR is not going to be retained as a functional Institute after reassignment of the CTSA program, that the DCM become part of the new NCATS.

Please do not hesitate to contact us at if we may provide additional information regarding our recommendations on the Straw Model.

Sincerely,



Phillip Scott, PhD
Professor *of* Immunology
Associate Dean *for* Research

Clinical Research FORUM
Analysis. Advocacy. Action.

SCTS Society for Clinical and Translational Science

ACRT Association for Clinical Research Training EST 2002

SGIM Society of General Internal Medicine

December 19, 2010

APOR
*Association for Patient-Oriented Research*

**Position Statement**

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

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

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

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

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

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

Sincerely;

Robert M. Califf, MD, Chairman
Clinical Research Forum
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(202) 775-0555

Harry P. Selker, MD, President
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Doris M. Rubio, Ph.D., President
Association for Clinical Research Training
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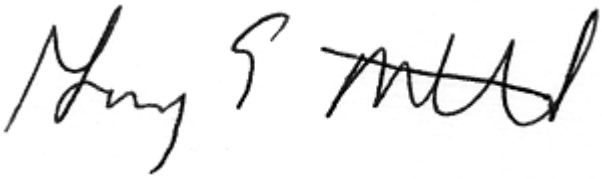

Gary Rosenthal, President
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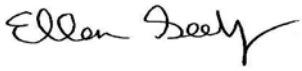

Ellen W. Seely, MD, President
Association for Patient-Oriented Research
4266 Bell Road, Suite 10
Newburgh, IN 47630
(800) 807-6444

THE UNIVERSITY OF UTAH

December 16, 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 Members of the Scientific Management Review Board,

Enclosed is a letter from NCRR Science Education Partnership Award (SEPA) grantees.

We urge the Scientific Management Review Board to ensure continued strong support and funding for this important program which supports diversification of the scientific workforce, contributes to the science education pipeline, enhances scientific literacy from K to grey, and educates the public about the mission of the National Institutes of Health.

Best regards,

Louisa A. Stark

Louisa A. Stark, Ph.D.
Director
Genetic Science Learning Center
University of Utah

Genetic Science Learning Center
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15 North 2030 East, Room 2160
Salt Lake City, Utah 84112-5330
(801) 585-3470

December 16, 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

Since the Dec. 7, 2010 public discussion of the creation of the National Center for Translational Medicine and Therapeutics, the future of the National Center for Research Resources (NCRR) and its programs has become somewhat uncertain. This raises concern about the continuation and vigor of a number of NCRR programs that we see as important to the research and educational communities nationwide.

Whatever form any NIH reorganization may ultimately take, we urge you to continue strong and coordinated support and funding for the Science Education Partnership Award (SEPA) program funded by NCRR. This nationally-recognized program is a vital investment in the our country's future, building a diverse scientific workforce pipeline, enhancing scientific and health literacy for people of all ages and promoting public support for the NIH.

Since 1992, the SEPA program has mobilized diverse scientific and medical resources to strengthen the nation's K-12 education system and promote science learning in formal and informal settings by people of all ages and backgrounds. Through exposure to genuine biomedical science, SEPA programs inspire diverse young people across the US to become the next generation of biomedical researchers and educators. The SEPA program has demonstrated extraordinary success in promoting access for all students—including those from groups underrepresented in science-related professions—to the latest discoveries and excitement of biomedical research. In addition, K-12 teachers who are exposed to the latest scientific discoveries and are trained in using high-quality science curriculum materials through SEPA programs are better prepared to teach and share their excitement about science with millions of students each year. Many of these teachers participate in the research programs themselves. Furthermore, exhibits and programs at science centers and museums also build science literacy by engaging community members of all ages. Other web, television and mutimedia resources also tell the stories of translational discovery. All of these SEPA programs engender public support for NIH and the public funding of

biomedical research. The SEPA program is already effectively addressing many of the 2010 recommendations on K-12 STEM education from the President's Council of Advisors on Science and Technology.

SEPA projects have received numerous awards that recognize their high quality and their significant contributions to science education. For example, this year the journal *Science* gave three of the first six Science Prize for Online Resources in Education (SPORE) awards to current or past SEPA grantees.

The SEPA community is unlike any other group of federal education grantees. We address K-12 science education in both formal and informal settings, provide a forum for educational innovation, rigorously evaluate educational outcomes and impacts, and are a proven vehicle for fostering community engagement in the NIH mission. Much synergy has been gained by gathering formal and informal K-12 programs into a single cohesive community that works together and learns from each other. The SEPA program is unique among federal programs in bringing together this diverse group and in building this synergy.

The signers of this letter represent the nationwide community of people who lead SEPA-funded projects. We are scientists, physicians, university and K-12 educators, science center and museum leaders, and scientific society staff. We believe strongly that NIH's promotion of science and health education through the SEPA program is highly successful despite a very modest annual budget, currently less than $25 million. It provides an indispensable positive contribution to the education and health of the American public. We thus urge you to continue strong support for a coherent SEPA program with funding at the current level or higher.

cc: Dr. Francis Collins, Director, NIH
Dr. Lawrence A. Tabak, Co-Chair, NCRR Task Force
Dr. Alan Guttmacher, Co-Chair, NCRR Task Force
Director's Council of Public Representatives

Lisa M. Abrams, Ph.D.
Associate Professor
Department of Foundations of Education
Virginia Commonwealth University

Walter C. Allan, MD
Medical Director
Foundation for Blood Research
and Consulting Scientist
*ScienceWorks for ME*

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Professor and Associate Dean for Engagement
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Barbara Baumstark, Ph.D.
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Judith S. Bond, PhD
Evan Pugh Professor and Chair
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Penn State University College of Medicine

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Gerry Boss, M.D.
Professor of Medicine
University of California, San Diego

Theresa B. Britschgi, MS
BioQuest Director
Seattle Biomedical Research Institute

Judy A. Brown
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Miami Science Museum

William E. Cameron, PhD
Associate Professor
Department of Behavioral Neuroscience
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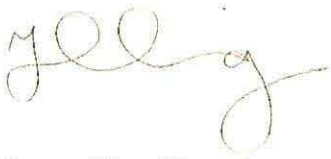
L. Arthur Campfield, Ph.D.
Professor, Food Science and Human Nutrition
COlorado State University

Charles Carlson
Project Director, Senior Scientist
Exploratorium

Ann Chester, Ph.D.
Assistant Vice President for Health Sciences for Social Justice
Robert C. Byrd Health Sciences Center
West Virginia University



Jeanne Ting Chowning
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Northwest Association for Biomedical Research

Toby Citrin
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University of Michigan School of Public Health

Theodore Clark, PhD
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Bridget C. Coughlin, PhD
Vice President
Denver Museum of Nature & Science

Valence Davillier
Vice President of Exhibits
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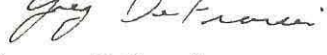
Maggie DeBon, Ph.D.
Associate Professor
University of Tennessee Health Science Center-Memphis
Department of Preventive Medicine

Dr. Sonsoles de Lacalle
Associate Professor
Charles Drew University of Medicine and Science



Gregory DeFrancis
Director of Education
Montshire Museum of Science

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Meharry Medical College

Donald A. DeRosa
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Boston University School of Education
Research Assistant Professor, Biochemistry
Boston University School of Medicine
PI of CityLab SEPA

Judy Diamond, Ph.D.
Professor and Curator
University of Nebraska State Museum

Erin L. Dolan, Ph.D.
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Outreach Director, Fralin Life Science Institute
Virginia Tech

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University of Southern Maine

Melani W. Duffrin, PhD, RD, LDN
Associate Professor of Nutrition Science
FoodMASTER Director
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Science Museum of Minnesota

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University of Nebraska Medical Center

SaVina Haywood
North Star – Principal Investigator
Anchorage Museum

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Director, MSOE Center for BioMolecular Modeling

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The University of Montana

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University of Illinois at Urbana-Champaign,

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University of Pittsburgh

Larry Johnson, PhD
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Professor of Veterinary Integrative Biosciences
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PI, SMART Program
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Michael Kennedy, PhD
Director, Science in Society – an office for science outreach & public engagement
Research Asst. Professor, Center for Genetic Medicine
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University of Florida

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Assistant Dean for Medical Education
Director, Center of Excellence for Research, Teaching, and Learning
Wake Forest University School of Medicine

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Bell Alcohol and Addictions Chair
University of Kentucky

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SEPA Principal Investigator
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Bertram Lubin, M.D.
President & Chief Executive Officer
Children's Hospital & Research Center Oakland

Naomi L. C. Luban, MD Chief,
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Director, Transfusion Medicine/
The Edward J. Miller Donor Center
Vice Chair for Academic Affairs,
Department of Pediatrics
Children's National Medical Center
Professor, Pediatrics and Pathology
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School of Medicine and Health Sciences

Dina Markowitz, Ph.D.
Professor of Environmental Medicine
Director, Center for Science Education and Outreach
University of Rochester

Laura W. Martin, Ph.D.
Senior Director of Educational Services
Arizona Science Center

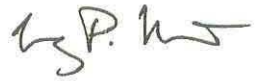
Marsha Lakes Matyas, Ph.D.
Director of Education Programs
American Physiological Society

Cheryl D. McCallum, Ed.D.
Director of Education
Children's Museum of Houston

Karina F. Meiri PhD, Professor of Anatomy and Cellular Biolgy, Neuroscience and Pharmacology, Director of the Integrated Studies Program,
Tufts University School of Medicine.

Leslie Miller, Ph.D.
Rice University
Center for Technology in Teaching and Learning

Marco Molinaro, Ph.D.
Chief Education Officer for the Center for Biophotonics, PI of the Science, Biostatistics, and Cancer Education SEPA grant, and Associate Program Director for K-16 outreach of the UCD CTSC
University of California, Davis (UCD) and the University of California, Davis, Health System.



Nancy P. Moreno, PhD
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Senior Associate Director, Center for Educational Outreach
Baylor College of Medicine

J. Steve Oliver
Professor and
Associate Department Head
Mathematics and Science Education
The University of Georgia

David H. Petering
SEPA program Director
University Distinguished Professor of Chemistry and Biochemistry
Director, NIEHS Children's Environmental Health Sciences Core Center
University of Wisconsin-Milwaukee

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Duquesne University Pittsburgh

David D. Potter, PhD
Robert Winthrop Professor of Neurobiology, emeritus
Department of Neurobiology
Harvard Medical School

Claudia L. Pryor
Principal Investigator / Executive Producer
Diversity Films Inc.

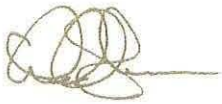
Carla Romney, D.Sc., M.B.A.
Assistant Dean, Graduate Medical Sciences
Associate Professor, Science and Engineering
Boston University School of Medicine
PI of CityLab SEPA

Patrice G. Saab, Ph.D.
Associate Professor
University of Miami

Joan F. Schanck, MPA
Director, Education and Workforce Development
Pittsburgh Tissue Engineering Initiative, Inc.

**Monique Scott**
**Assistant Director of Cultural Education**
**American Museum of Natural History**

Virginia L. Shepherd, Ph.D.
Professor of Pathology
Director, Center for Science Outreach
Vanderbilt University
Senior Career Scientist
VA Medical Center



Linda S. Shore, Ed.D
Director, Teacher Institute
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Rebecca Smith, PhD
Co-Director
Science & Health Education Partnership
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Louisa A. Stark, Ph.D.
Director, Genetic Science Learning Center
Associate Director, Community Engagement Core,
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Kimberly D. Tanner, Ph.D.
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Director, SEPAL: The Science Education Partnership
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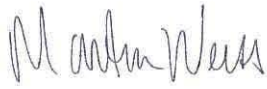
Patricia A. Thomas, M.D
Professor of Pathology
Associate Dean
Office of Cultural Enhancement and Diversity
University of Kansas School of Medicine

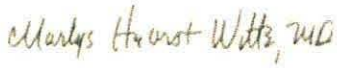


Martin Weiss, PhD
Science Interpretation
New York Hall of Science

Marilyn A. Winkleby, Ph.D., MPH
Professor of Medicine
Stanford Prevention Research Center
Faculty Director, Office of Community Health
Stanford University School of Medicine



Kelley Withy MD, PhD
Professor, Dept. Complementary/Alternative Medicine
University of Hawaii John A. Burns School of Medicine
Director, Hawaii/Pacific Area Health Education Center



Marlys H. Witte, MD
Professor of Surgery
Director, Student Research Programs
University of Arizona College of Medicine

Charles A. Wood, PhD
Executive Director, Center for Educational Technologies
Wheeling Jesuit University

Eve Syrkin Wurtele
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Norman Augustine
Attn: Lyric Jorgenson
Office of Science Policy
Office of the Director
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

February 23, 2011

Dear Mr. Augustine:

Genetic Alliance supports the newly proposed National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health.

We are a network of health organizations, numbering more than 10,000 organizations, and we are committed to improving human health outcomes including accelerating the development of new therapeutic options for patients and consumers. The Genetic Alliance network includes more than 1,200 disease-specific advocacy organizations representing the millions of Americans affected by disease. For them there is an urgent need to bring the promise of translation to fruition. Last year, despite more than 100 billion dollars in research spending, only 20 drugs came to market. This is much too slow and needs to be vastly improved. Further, fewer than 200 of the 7,000 rare diseases have any available therapy options. The current system of therapeutic development has been failing patients and consumers for far too long and the time to transform translational medicine is upon us.

Genetic Alliance believes that the National Institutes of Health (NIH) has both the potential and the responsibility to leverage its existing and emerging programs and resources to accelerate translational medicine. The passage of the Cures Acceleration Network highlights that both the American public and Congress share this expectation that NIH will play a leading role in improving human health outcomes through translational research.

Genetic Alliance supports the newly proposed NCATS because it offers an unparalleled opportunity to advance translational medicine and improve human health. Currently, there are a number of programs spread across the NIH that are tailored to the goal of translating basic research into therapeutics, including the Molecular Libraries Program, Therapeutics for Rare and Neglected Diseases Program, NIH Rapid Access to Interventional Development Program, the Clinical and Translational Science Awards, and the NIH-FDA Regulatory Science Initiative. The

In addition, even as NIH takes this critical focused approach to drive drug development, it is important that we remember the broad needs of translation, including the meaningful involvement of individuals, families, and communities in the process and effective engagement of the public. The excellent work done as part of the Clinical and Translational Science Awards in the area of community engagement should not be lost and the trans-NIH movement to increase a broad focus on translation should continue to be encouraged as part of the new Center and beyond.

Genetic Alliance works with all of the Federal agencies charged with promoting the nation's health. We determined long ago that there are enormous silos preventing the coordination essential to developing timely and robust diagnostics and therapies. We have identified steps to accelerating translational research and the NCATS is essential for this mission.

We thank you for your continued interest and support for translational medicine. The men, woman and children who live day in and day out with these diseases are depending on your leadership. It is incumbent upon us to make a difference and, as a nation we have the tools to do so. It is time for NIH to claim responsibility for accelerating translation. Let's work together to realize the promise that lies before us in a multitude of sciences that are ready to come to fruition in the form of solutions for those who suffer.

Thank you,

Sharon Terry
President and CEO
Genetic Alliance

Tufts
UNIVERSITY

**Cummings School of Veterinary Medicine**

February 15, 2011

Drs. Lawrence Tabak and Alan Guttmacher
Co-Chairs, NCRR Task Force
Office of the Director
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892
smrb@mail.nih.gov

Dear Co-Chairs Tabak and Guttmacher, and Members of the NIH NCRR Task Force:

On behalf of Tufts University Cummings School of Veterinary Medicine, we are writing this letter to provide comments and recommendations on the National Center for Research Resources (NCRR) Task Force Straw Model showing the proposed new National Institutes of Health (NIH) homes for current NCRR programs.

We recognize the importance of the NIH's initiative to create the National Center for Advancing Translational Sciences (NCATS), and welcome the potential benefits to our nation's health of an invigorated focus on translational medicine and therapeutics. Our faculty members are proud of their significant contributions toward improving human health through transdisciplinary involvement and collaboration in translational research and comparative medicine. The support offered by NCRR programs (T35 and T32 training grants) and resources (renovation of laboratory animal facilities) to our institution have made possible their important contributions to our nation's health, and we greatly appreciate the opportunity to provide comment and recommendations to further advance the successes of critical NCRR programs.

In review of the Straw Model, we have the following comments:

1. To successfully fulfill its mission of accelerating the development and delivery of new, more effective therapeutics, the NCATS will rely on a diversity of appropriately trained laboratory scientists and clinical researchers capitalizing on the development of tools and technologies and making discoveries at molecular and cellular levels that can be tested and proven in animal based studies.

2. Although a logical and rational argument can be made for including NCRR's Clinical and Translational Science Award (CTSA) program, which is designed to develop teams of investigators from various fields of research who can transform scientific discoveries made in the laboratory into treatments and strategies for patients in the clinic, into the new NCATS, the same cannot be said for excluding and dismembering other components of NCRR, such as animal resources, training programs, and high-end instrumentation and technologies which are so critical to NCATS mission.

3. Further, as indicated in the NCRR Task Force Straw Model, proposing to subdivide these other NCRR components disrupts the extant scientific synergies that have been demonstrated meritorious to date, and forfeits the strategic relationships that have been built between programs over the last 20 years. For example, splitting the animal

resources into different administrative structures erects a bureaucratic obstacle that needlessly hinders the flow of basic scientific discoveries made in induced genetic mutations in mice to clinically applicable mechanisms-of-action studied and tested in non-human primates.

4. Although it is expected that following this restructuring, NCRR will no longer exist as a center, a rational consideration would be to maintain a large component of NCRR programs together after reassignment of the CTSA program within the new NCATS. Those charged with making these decisions should be mindful that NCRR's unique, cross-cutting programs are and have been successful through careful planning, thoughtful leadership, and effective management by its administrative and scientific staff, program officers, and officials who understand these programs and are most qualified to ensure continued success of their respective programs and initiatives.

We therefore strongly recommend that the NCRR's Division of Comparative Medicine (both programs and staff) be retained as a functional entity after reassignment of the CTSA program. The optimal location of the unit within the NIH (e.g., NCATS, National Institute of General Medical Sciences, or Office of the Director), should be carefully deliberated with input from NCRR staff and stakeholders.

Please do not hesitate to contact us if we may provide additional information regarding our recommendations on the Straw Model.

Sincerely,

Deborah T. Kochevar, DVM, PhD, DACVCP
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Office of the Dean

College of Veterinary Medicine

Athens, Georgia 30602-7371
Telephone 706-542-3461
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February 21, 2011

Mr. Norman Augustine
Chair, Scientific Management Review Board
Office of the Director
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892
smrb@mail.nih.gov

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

As the Dean and Associate Dean, Research and Graduate Affairs at the University of Georgia College of Veterinary Medicine (UGA CVM), we write this letter on behalf of our College to provide comments and recommendations on the National Center for Research Resources (NCRR) Task Force Straw Model showing the proposed new National Institutes of Health (NIH) homes for current NCRR programs.

The UGA CVM recognizes the importance of the NIH's initiative to create the National Center for Advancing Translational Sciences (NCATS), and understands the potential benefits to the nation's health of an invigorated focus on translational medicine. Our faculty is proud of the College's contributions toward improving human health through interdisciplinary involvement and collaboration in translational research and comparative medicine. The support offered by NCRR programs and resources, which include our College's T35 veterinary student training program and the NCRR's R13 support for the National Veterinary Scholars Symposium, "Veterinarians in Biomedical Research: Building Capacity" have made important contributions to our nation's health through the training of new veterinary researchers. We appreciate the opportunity to provide comment and recommendations to further advance the successes of NCRR programs.

In review of the Straw Model, we convey the following comments:

1. To successfully fulfill its mission of accelerating the development and delivery of new, more effective therapeutics, the NCATS will rely on a diversity of appropriately trained laboratory scientists and clinical researchers capitalizing on the development of tools and technologies and making discoveries at molecular and cellular levels that can be tested and proven in animal based studies.

2. Although a logical and rational argument can be made for including NCRR's Clinical and Translational Science Award (CTSA) program, which is designed to develop teams of investigators from various fields of research who can transform scientific discoveries made in the laboratory into treatments and strategies for patients in the clinic, into the new NCATS, the same cannot be said for excluding and dismembering other components of NCRR, such as animal resources, training programs, and high-end instrumentation and technologies which are so critical to NCATS mission.

3. Further, as indicated in the NCRR Task Force Straw Model, proposing to subdivide these other NCRR components disrupts the extant scientific synergies that have been demonstrated meritorious to date, and forfeits the strategic relationships that have been built between programs over the last 20 years. For example, splitting the animal resources into different administrative structures erects a bureaucratic obstacle that needlessly hinders the flow of basic scientific discoveries made in induced genetic mutations in mice to clinically applicable mechanisms-of-action studied and tested in non-human primates.

4. Although it is expected that following this restructuring, NCRR will no longer exist as a center, a rational consideration would be to maintain a large component of NCRR programs together after reassignment of the CTSA program within the new NCATS. Those charged with making these decisions should be mindful that NCRR's unique, cross-cutting programs are and have been successful through careful planning, thoughtful leadership, and effective management by its administrative and scientific staff, program officers, and officials who understand these programs and are most qualified to ensure continued success of their respective programs and initiatives.

We recommend that the NCRR's Division of Comparative Medicine (both programs and staff) be retained as a functional entity after reassignment of the CTSA program. The optimal location of the unit within the NIH (e.g., NCATS, National Institute of General Medical Sciences, or Office of the Director), should be carefully deliberated with input from NCRR staff and stakeholders.

Please do not hesitate to contact us at (706) 542-5734 or hwd@uga.edu if we can provide additional information regarding recommendations on the Straw Model.

Sincerely,

Sheila W. Allen, DVM, MS
Dean

Harry W. Dickerson, BVSc., PhD
Associate Dean, Research and Graduate Affairs

UNIVERSITY OF ILLINOIS
AT URBANA-CHAMPAIGN

**College of Veterinary Medicine**

Office of the Dean
3505 Veterinary Medicine Basic Sciences Building
2001 South Lincoln Avenue
Urbana, IL 61802

February 16, 2011

Drs. Lawrence Tabak and Alan Guttmacher
Co-Chairs, NCRR Task Force
Office of the Director
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892
smrb@mail.nih.gov

Dear Co-Chairs Tabak and Guttmacher, and Members of the NIH NCRR Task Force:

On behalf of the University of Illinois College of Veterinary Medicine, we are pleased to provide comments and recommendations on the National Center for Research Resources (NCRR) Task Force Straw Model showing the proposed new National Institutes of Health (NIH) homes for current NCRR programs.

We recognize the importance of the NIH's initiative to create the National Center for Advancing Translational Sciences (NCATS), and welcome the potential benefits to our nation's health of an invigorated focus on translational medicine and therapeutics. The faculty of the University of Illinois College of Veterinary Medicine are proud of their significant contributions toward improving human health through transdisciplinary involvement and collaboration in translational research and comparative medicine. The support offered by NCRR programs and resources to our institution and faculty have made possible their important contributions to our nation's health, and we greatly appreciate the opportunity to provide comment and recommendations to further advance the successes of critical NCRR programs. Specifically, the College was awarded an NCRR grant (#C06 RR16515-01), *UIUC College of Veterinary Medicine Completion Shell Space*, in the amount of $1,476,324. This award assisted the college in developing new research space to accommodate NIH-funded research in the areas of infectious disease and reproductive, developmental and endocrine toxicology. The program model allowed us to easily identify the appropriate NIH institute to interact with and seek advice for funding of our project. Therefore, our recommendation is to maintain the Division of Comparative Medicine as a unit during your deliberations for potential reassignment.

In review of the Straw Model, we have the following comments:

1. To successfully fulfill its mission of accelerating the development and delivery of new, more effective therapeutics, the NCATS will rely on a diversity of appropriately trained laboratory scientists and clinical researchers capitalizing on the development of tools and technologies and making discoveries at molecular and cellular levels that can be tested and proven in animal based studies.

2. Although a logical and rational argument can be made for including NCRR's Clinical and Translational Science Award (CTSA) program, which is designed to develop teams of investigators from various fields of research who can transform scientific discoveries made in the laboratory into treatments and strategies for patients in the clinic, into the new NCATS, the same cannot be said for excluding and dismembering other components of NCRR, such as animal resources, training programs, and high-end instrumentation and technologies which are so critical to NCATS mission.

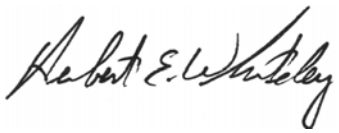
3. Further, as indicated in the NCRR Task Force Straw Model, proposing to subdivide these other NCRR components disrupts the extant scientific synergies that have been demonstrated meritorious to date, and forfeits the strategic relationships that have been built between programs over the last 20 years. For example, splitting the animal resources into different administrative structures erects a bureaucratic obstacle that needlessly hinders the flow of basic scientific discoveries made in induced genetic mutations in mice to clinically applicable mechanisms-of-action studied and tested in non-human primates.

4. Although it is expected that following this restructuring, NCRR will no longer exist as a center, a rational consideration would be to maintain a large component of NCRR programs together after reassignment of the CTSA program within the new NCATS. Those charged with making these decisions should be mindful that NCRR's unique, cross-cutting programs are and have been successful through careful planning, thoughtful leadership, and effective management by its administrative and scientific staff, program officers, and officials who understand these programs and are most qualified to ensure continued success of their respective programs and initiatives.

We therefore strongly recommend that the NCRR's Division of Comparative Medicine (both programs and staff) be retained as a functional entity after reassignment of the CTSA program. The optimal location of the unit within the NIH (e.g., NCATS, National Institute of General Medical Sciences, or Office of the Director), should be carefully deliberated with input from NCRR staff and stakeholders.

Please do not hesitate to contact us at 217/333-2760 or lhoyer@illinois.edu or hwhitele@illinois.edu if we may provide additional information regarding our recommendations on the Straw Model.

Sincerely,



Lois L. Hoyer, MS, PhD
Associate Dean for Research
and Advanced Studies

Herbert E. Whiteley, DVM, PhD
Dean

Kelley Withy, MD, PhD
571 Kaimalino St.
Kailua, HI 96734
808-429-8712

February 15, 2011

National Institutes of Health

RE: The proposal to create a new center for advancing translational medicine and therapeutics development and its impact on other programs at NIH, including the National Center for Research Resources.

To NIH Scientific Management Review Board:

I am writing to express my strong support for moving the NCRR Science Education Partnership Award program to the Office of the Director. This is a very important program that works to alert kids to science and scientific research at a young age, whether through in-class activities or science centers. I am a grantee, and much of my emphasis is on the US Affiliated Pacific Island Countries, particularly the Federated States of Micronesia. These areas are the developing countries under the protection of the US. However the educational infrastructure is not up to the US level. In fact, some of the classrooms that I saw when visiting our teachers last week did not have electricity.

Unfortunately these islands are sinking (or the water level is rising)! People there have little knowledge of conservation, resource utilization, microbiology, immunology, infectious disease or marine science. If anyone needs to understand oceanography, it is the people of Micronesia. However there is no standard science curriculum, much less microscopes for science training. There is no science infrastructure, so little interest and awareness of the possibilities. Therefore we are working with the 8$^{th}$ and 9$^{th}$ grade science teachers to get them the necessary training and resources to teach inquiry based science that incorporates career awareness. We believe this will empower the people of Micronesia to improve both themselves and their country. Without the assistance of educational programs such as SEPA, there will be minimal chance of advancement in science in the region.

Thank you for allowing me to express my support for maintaining the SEPA program and locating it in the Office of the Director.

Sincerely,

Kelley Withy, MD, PhD
University of Hawaii, John Burns School of Medicine