

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 12th 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 agencies” for some NCRR programs. Of course, the creation of these new agencies requires the loss of existing agencies within NCRR, the perceived value of which has been one of the strongest themes emerging from the public comments. The issue of agencies 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 a center and possible structural models. 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.