

Dear Council Members:

Since NIGMS launched the Glue Grants initiative more than 10 years ago, the Institute has watched the program develop, grow and yield scientific advances relevant to the NIGMS mission. As you know, in 2008 I requested that a process evaluation be conducted to assess Glue Grant program design, management and implementation. A draft of this report was shared with you at our January 2010 Council . It is now being finalized for public release.

In the meantime, NIGMS has carefully considered the findings and recommendations provided by the Science and Technology Policy Institute. As a result, we will be making some changes in program management, the details of which are outlined in the attached NIGMS response to the report. We believe that although no process is flawless, an unbiased view from an independent source has nonetheless been quite valuable

Once again, I thank you for your contributions in one of the Institute's major programs. As we move forward on implementing some of the report's recommendations, I look forward to hearing your advice and perspective.

Sincerely yours,

Jeremy M. Berg, Ph.D.

Director, NIGMS

**Science and Technology Policy Institute Process Evaluation of the NIGMS Glue Grant Program:  
NIGMS Response to Final Report  
May 18, 2010**

**Introduction**

Between FY 2000 and FY 2009, NIGMS invested approximately \$336 million into its Large-Scale Collaborative Project Awards, commonly known as Glue Grants. Now more than 10 years old, the NIGMS Glue Grants program has grown and yielded important scientific advances relevant to the NIGMS mission. Given the significant investment in the program, NIGMS Director Dr. Jeremy Berg requested a two-phase program evaluation: 1) a process evaluation to examine the design, management and implementation of the Glue Grants program and 2) an assessment of the scientific impact.

The Science and Technology Policy Institute (STPI), a Federally Funded Research and Development Center, was selected to conduct the Process Evaluation as an independent evaluator with guidance from an Advisory Committee consisting of senior NIGMS staff members. The process evaluation conducted by STPI is now complete, and we are preparing to publicly release the report's findings, which provide useful information to consider as we make programmatic and funding decisions.

This document — the Institute's response to the report — provides a context for our decisions on the issues raised in the process evaluation. Although no process is flawless, we believe that an unbiased investigation from an independent source has been valuable in helping the Institute evaluate the program's development and implementation strategies.

Views expressed within this response represent those of the Institute as a whole. They were informed not only by the NIGMS Director and senior leadership; but by NIGMS staff and senior management involved with the Glue Grant projects. Since the program announcement for the Glue Grant initiative has expired, the Institute is primarily focused on changes that can be implemented for current and pending awards. It should be noted however that NIGMS is currently planning for phase two—the assessment of scientific output.

**STPI Findings**

Findings noted in the report resonate thematically, addressing three main concepts: 1) definition of the study problem and approach; 2) tailoring the strategy and objectives; and 3) management issues inherent to programs of large size and scope.

**1. Definition of the study problem and approach**

*Finding 1: The program-level objectives of the Glue Grants were not clear.*

*Finding 2: The program design as implemented was not entirely consistent with either of the stated program objectives.*

In launching its Glue Grant initiative, NIGMS sought to allow applicants to present and attempt to solve research problems significant to various fields of biomedicine as defined by researchers, those “in the trenches.” Although NIGMS-led review endorsed the mix of breadth and depth of the defined problems selected, as well as the overall objectives to solve them, the ensuing research process was left open to interpretation by awardees who could best assess and meet the needs of their individual fields and specific circumstances. If anything, in making a funding decision, the Institute leaned toward grander rather than smaller challenges, given the scope and time-frame of the awards.

## **2. Tailoring the strategy and objectives**

*Finding 3: In the absence of clear program objectives, the Glue Grant consortia were structured to meet needs and priorities as determined at the consortium level.*

*Finding 4: The Glue Grants functioned as a funding mechanism rather than as a cohesive program or initiative.*

As the process evaluation notes, after 10 years we recognize that providing such flexibility to applicants did have consequences for the management of individual awards as well as for oversight of the overall program. In large part, this is a perspective gained in hindsight; certainly, NIGMS and the larger biomedical research community acknowledges the value of self-assembly in the ability of scientific teams to solve problems around a common interest. However, less clear is how to endorse a particular problem as one that successfully strikes a balance between being sufficiently difficult yet potentially solvable. One important insight from this set of findings is that NIGMS could have been more explicit that Glue Grant awards should result in important, qualitative advances towards the solution of a major biomedical problem — or in moving a field towards its solution — that cannot be achieved by investigators working independently. The task is even more confounded by a basic principle of the NIGMS mission — that the best science comes from investigator-initiated proposals that select and address key topics and develop the cutting-edge tools that individual fields need.

NIGMS oversight of the individual Glue Grants may have exceeded that for typical research project grants because many unanticipated needs arose throughout the lifetime of the awards, and these needs usually pointed to the need for additional resources. One prime example is the costly but rate-limiting bioinformatics support, which became apparent for most projects, and is emblematic of the needs of the ‘omic’ age. Although NIGMS staff met regularly to share experiences about Glue Grant management and other issues, noting common problems and suggesting potential solutions, no one individual or committee had been charged with the authority to make decisions about all of the individual Glue Grant awards.

## **3. Management issues inherent to programs of large size and scope**

*Finding 5: The 10-year time-frame posed a variety of challenges.*

*Finding 6: Significant challenges for peer review were encountered because of the size and scope of the Glue Grants.*

*Finding 7: The NIGMS approach to management of the Glue cooperative agreements was not adequately defined.*

Sponsoring any large-scale, long-term investment faces the dual challenges of requiring flexibility to accommodate progress and failure, and necessitating milestones for progress. While NIGMS remains convinced that the Glue Grant concept has considerable merit, and that there is value added in providing substantial resources to a community of scientists aiming to define and solve a problem of major importance, the challenge lies in the ability to detect those areas most ripe for an integrative approach.

### **Program Strategies Proposed by STPI**

In its final report, STPI also offered four strategic options available to NIGMS with respect to program design and management. All but one of these options includes additional specific recommendations based on STPI's findings. In this section, NIGMS responds to each option and its concomitant recommendations noting a plan of action and proposed indicators to measure the impact of program changes.

**Option 1: Allow the current Glue Grant funding solicitation to expire and do not fund any new awards.**

**Response:** Pending a scientific assessment of the program outputs and impact, the Institute reserves judgment on the future of the Glue Grant initiative.

**Option 2: Continue to fund and manage the Glue Grants as individual cooperative agreements within the context of existing NIGMS research portfolios.**

**Recommendation 2-1: Require the funded consortia to set achievable goals, and consider requiring them to develop post-award strategic plans for approval by NIGMS.**

**Response:** Milestones are currently required as a part of Glue Grant Phase II applications and are updated in annual progress reports, which are reported to Council annually for each funded award. Since the NIGMS Glue Grants were initiated in 1999, several other large-scale programs have been launched at NIH and elsewhere, providing an opportunity to ascertain best practices. If NIGMS determines it will reannounce the initiative, the Institute will consider building formal evaluation indicators into each glue grant as it is funded, developed in conjunction with the NIGMS Office of Program Analysis and Evaluation (OPAE).

**Action Plan:** NIGMS recently began a brown-bag lunch series, inviting managers of large grants programs from other NIH Institutes and Centers to present and discuss their respective programs and associated issues related to research resources, personnel challenges and other aspects of team science.

**Indicators:** The brown-bag sessions will be held at least four times per year, and NIGMS staff who attends will record, then report best practices and challenges with NIGMS senior leadership.

**Recommendation 2-2: Formalize administrative review processes during Phase II of the Glue Grant awards.**

**Response:** NIGMS concurs.

**Action plan:** For two new awards, plans for administrative reviews by staff and peer experts have been made “conditions” of award: at 18 months, to assess how well the project has been assembled and whether forward progress is now in full swing; and at 36 months, to assess progress and whether the program is on track to achieve its objectives. The Institute will implement an administrative review that includes staff and peer experts three years into the Phase II renewal period of all funded Glue Grants.

**Indicators:** Establish a timeline for administrative review and report findings to NIGMS senior leadership.

**Recommendation 2-3: Re-think expectations for Phase I of Glue Grants in order to reduce ramp-up time and unexpected technical difficulties during Phase II, and adjust budget limits as necessary.**

**Response:** Specific terms of the two phases of extant Glue Grants are delineated within the current funding solicitation. Currently, Phase I awards are \$50,000 planning grants whose purpose is to earn an applicant approval to submit a Phase II full Glue Grant application, plus funding to enable meetings and communication amongst leadership and participating investigators toward assembling the full proposal. As stated, applicants may set budgets lower in the early years of the Phase II award without reducing the overall five-year budget for the Glue Grant. NIGMS staff are thus constrained in the ability to restore funds in later years, unless the budget specifies such action.

**Action Plan:** Staff will continue to make budget adjustments to current Phase II awards as appropriate to the project and within the allowances of the funding solicitation. If NIGMS determines it will reannounce the Glue Grants initiative, the Institute will consider changing the Phase I application to include information about the validity of the project. In addition, NIGMS will consider requiring “go/no-go” milestones negotiated early into the Phase II award period.

Progress towards or achievement of such milestones could be assessed by staff, outside experts, and Council at an appropriate interval.

**Indicators:** Monitor and document any budget changes made to Phase II applications and report to NIGMS senior leadership.

**Recommendation 2-4: Consider lifting the sunset provision or providing an alternative means of continued support for collaborative efforts after the first 10 years.**

**Response:** As science evolves and health needs shift, NIH components must remain nimble in their ability to fund new programs. Thus, NIGMS believes that, in general, the sunset provision represents a healthy and effective mechanism for limiting the overall investment in any one program over the long term. However, we do acknowledge that the sunset provision of the Glue Grant program has had several unanticipated consequences. We have noted, for example, that the most problematic of these issues has been, in some cases, the waning commitment of Glue Grant investigators to work toward the final goals of the project as they move closer to the termination of the award. In the current configuration of the Glue Grant concept, and dependent on individual projects, it has been difficult for NIGMS to prevent this waning interest and commitment to project milestones.

**Action Plan:** NIGMS is considering a strategy that requires a mid-term evaluation in Phase II, with agreed-upon milestones. Funding of the final two years of the awards would be contingent upon whether the project successfully attains its milestones. Another strategy under debate is to provide several options for follow-on transitional awards to allow preservation of resources or valuable collaborations created during the 10-year Glue Grant. These follow-on awards would be on a much smaller scale and would be designed to preserve only the most valuable elements of each award while the investigators transition to an independent award or more traditional grant support. The Institute will also develop revised requirements for the end of year-9 progress reports to include questions about measures of success for that particular Glue Grant, specific success(es) of the Glue Grant to date, and success anticipated at the conclusion of the project.

**Indicators:** We anticipate that NIGMS staff will report to the National Advisory General Medical Sciences Council a summary of any research resources that result from Glue Grants and their sources of support).

**Recommendation 2-5: Address the issue of sustainability for consortium-developed resources.**

**Response:** NIGMS concurs.

**Action Plan:** The Institute is actively developing an initiative to preserve resources generated through NIGMS-supported initiatives such as Glue Grants. This initiative will be presented to the National Advisory General Medical Sciences Council.

**Indicators:** The numbers of applications and awards for the new initiative will serve as indicators for need and relevance of the program. In addition, metrics for evaluation will be built into the program with the aid of the NIGMS Program Analysis and Evaluation Office.

**Option 3: Take steps to transform the Glue Grants from a mechanism to a true initiative with clear goals and consistent, centralized management practices.**

**Recommendation 3-1: Articulate a rationale, clear program goals, as well as a theory of action for the Glue Grants.**

**Response:** Pending a scientific assessment of the program outputs and impact, the Institute reserves judgment on the future of the Glue Grant initiative. Should the program continue, NIGMS will carefully consider the findings and recommendations of the STPI process evaluation as well as the scientific review findings in order to further clarify the intent and goals of the program.

**Recommendation 3-2: Centralize leadership, management, and oversight of the Glue Grant program/initiative.**

**Response:** Because NIGMS has managed the Glue Grant program primarily as a funding mechanism, as per Institute practice and policy, individual awards are managed by program staff with the most relevant scientific background. We recognized early on, however, inconsistency that results from this approach and thus employed an additional, Glue Grant committee strategy for broader analysis. A more formal role for this entity — with explicit responsibilities — is being considered in order to improve the Institute’s ability to manage the individual Glue grants more evenly.

**Action Plan:** NIGMS will draft a charter for the Glue Grant committee, stating its charge and operating procedures.

**Indicators:** The committee will begin to operate formally upon the NIGMS Director’s approval of its charter.

**Recommendation 3-3: Encourage formation of a ‘network’ of funded consortia.**

**Response:** Although the Institute supports the sharing of ideas and best practices among Glue Grant awardees, the diversity of science and approaches may discourage a meaningful scientific exchange on a formal, recurring basis. However, NIGMS staff remains attentive to common problems and needs and share these issues within the Institute and with relevant Glue Grant participants on an as-needed basis.

**Action Plan:** NIGMS staff have met with Glue Grant researchers on occasion to discuss common issues, such as bioinformatics needs and to discuss arrangements for sustaining resources beyond expiration of funding. As the science and interest has dictated, collaborations have self-assembled between funded Glue Grants, independent of NIGMS involvement.

**Indicators:** Issue-specific meetings of the Glue Grants will be monitored, recorded, and reported to the National Advisory General Medical Sciences Council.

**Recommendation 3-4: Implement mechanisms for collecting data sufficient to monitor progress towards program goals.**

**Response:** Pending an outcomes assessment of the program, the Institute reserves judgment on the future of the Glue Grant initiative.

**Option 4: Identify the components of core functionality provided by the Glue Grants that are priorities for NIGMS, and build smaller programs around each component.**

**Response:** Pending an outcomes assessment of the program, the Institute reserves judgment on the future of the Glue Grant initiative.

### **Future Evaluation Efforts: The Phase Two Scientific Review**

As noted in STPI's process evaluation final report:

*"The size, scope, and visibility of the Glue Grants suggest that an outcome evaluation is almost certainly warranted in order to assess the value provided by the program to NIGMS and the extramural community. However, the process evaluation identified a number of factors that are likely to pose significant challenges for the feasibility of a program-level outcome evaluation of the Glue Grants. These include:*

- *The small number of funded consortia (five) relative to the high degree of heterogeneity with respect to consortium organization, goals, activities, and outputs;*
- *The apparent absence of a common set of objectives or theory of action across the program;*
- *The lack of standards or suitable comparison groups against which to measure progress.*

*While a feasibility study would be required to explore these issues in detail, the sense of the evaluators who conducted the process evaluation is that program-level evaluation of Glue Grant outcomes would be an extremely difficult undertaking, and there is a high risk that any results would be misleading."*



**Response:** Although a formal outcomes evaluation of the Glue Grant program as a whole is not feasible , NIGMS supports an assessment of the value, research and resources of each of the Glue Grant projects. We believe that insights gained from this endeavor will help illuminate what the results of the Glue Grant approach have been so far, as well as help to determine whether those results and likely future outcomes justify continuing the initiative.

**Action Plan:** NIGMS will convene an expert panel to assess the Glue Grants in December 2010. The panel will consist of individuals with appropriate expertise as well as a broad scientific background. It will be important that potential candidates for the panel be screened for significant philosophical differences or for being invested in a particular Glue Grant project. We expect that at least one individual on the panel will be a current or former Advisory Council member.

**Indicators:** The panel deliberations will be transcribed and recorded. A written report will be developed regarding the proceedings of the meeting and the subsequent findings. The report will be presented at the May 2011 meeting of the NIGMS Advisory Council and used by NIGMS to help decide whether to continue the Glue Grants initiative.