Support Services Task1: Assessment of Advisory Council Functions

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Executive Summary

The Advisory Council (Council) at the National Institute for General Medical Sciences (NIGMS) has two functions: (1) to perform second-level peer review of grant applications assigned to NIGMS and (2) to advice on policy, program development, and other areas of importance to the NIGMS mission and goals. The Council roster includes extramural scientists specializing in areas relevant to the Institute, lay members with specific expertise, and representatives from the U.S. Department of Veterans Affairs and the U.S. Department of Defense. Members are appointed for 4-year terms and meet three times a year for a day and a half. Procedures for Council formation as well as Council's composition and roles are governed by federal law and the NIGMS charter.

At present, NIGMS staff members view the level of Council participation in advising the Institute on scientific research and policy as somewhat limited. Abt Associates was charged with examining the Council's functions to identify strategies to more effectively engage Council in this area. To accomplish this task, we posed the following research questions:

- How are Council members identified and prepared for service? What information and materials would Council members find useful to prepare them for service?
- Is there a clear understanding among Council members and NIGMS staff about Council roles and responsibilities?
- What processes and procedures are in place to facilitate Council's advisory role to NIGMS on matters of science and policy? How can these be changed to engage Council more fully and more systematically?
- Are there any aspects of the communication between Council and NIGMS staff that need to be enhanced?
- What are the models for engaging advisory councils at other NIH Institutes and outside of NIH? Are these models applicable to the NIGMS Council?

Data to answer these questions were gathered through semi-structured interviews with 14 NIGMS staff, 16 Council members, five Executive Secretaries at the NIH institutes, two representatives from the National Science Foundation (NSF), and one representative from the Howard Hughes Medical Institute (HHMI), as well as through analyses of a variety of existing materials describing advisory councils.

The majority of respondents expressed positive views about the NIGMS Council. Several NIGMS staff believed that the Council was "basically appropriate" and "not dramatically out of balance." Executive Secretaries at other NIH Institutes characterized NIGMS Council as well-run or exemplary. Nearly 90% of Council members were satisfied with their service; many singled out NIGMS commitment to supporting the best science and easy access to the staff, including the Institute Director.

At NIGMS, candidates for Council are proposed by the staff and vetted by the Director. New members are provided with a variety of materials describing Council roles and responsibilities and are briefed by the Institute on the phone and in person. Despite the steps taken by the Institute to ease the assimilation of new Council members, many respondents reported being unprepared for

what took place in their first meeting. The biggest challenge identified both by the members and by NIGMS staff was the large amount of material (hundreds of pages) that Council is asked to review before each session. NIGMS respondents were aware that Council members might be overwhelmed by the assignments, but expressed some reluctance to offer explicit directions to avoid biasing the members. However, when asked, some division directors do offer advice on how to prioritize the assignments.

NIGMS staff had different views on the appropriate use of Council. Some respondents thought that Council was better at providing policy advice than scientific guidance; others advocated for greater Council participation in both policy and in science; yet others were satisfied with the status quo. Regardless of their position on the use of Council, the majority of NIGMS staff believed that Council was not fully engaged and that the Institute was not taking advantage of the talent and knowledge that Council has to offer. This view was shared by Council members.

During the sessions, Council has several opportunities to give broader advice: at breakout sessions, concept clearance, and Council-initiated discussion. However, in-depth discussions are rare. We identified two factors that might limit Council's advisory role. First, NIGMS has not clearly conveyed to Council that input on setting research directions was being sought. A third of Council members (n=15) viewed Council as mainly responsible for secondary level review and another 20% were unsure of Council role. Furthermore, in some cases, the Institute may have created an impression that advice was unwelcome. Several Council members noted that program directors often appeared vested in ideas by the time they were brought up to Council and did not seem receptive to suggestions. Second, the format of Council does not lend itself to proactive engagement. The agenda for each meeting is full and the time allotted for Council-initiated discussion is scheduled for the very end of each proceeding. We also found that Council time is not always used most efficiently, as some staff presentations are too long relative to their importance to NIGMS.

Council members we interviewed noted that the level of engagement beyond secondary review of applications was commensurate with the commitment of individual members and that those interested in influencing science or policy at the Institute found opportunities to be involved. Occasionally, Council as a group became active, generally when an issue was directly relevant to the members, such as peer review policies.

Almost all Council members were able to give a specific example of Council advice on policy or science matters, although sometimes they were unsure whether the advice has been taken by NIGMS. These examples included shaping the Glue Grant Program and the Protein Structure Initiative, conveying concerns on the new application scoring system, and advising NIGMS on training programs. However, most Council members would have preferred to have greater involvement and impact in substantive areas.

The level of communication between NIGMS and Council outside of the sessions varied. Some Council members regularly interacted with NIGMS program directors and senior management to discuss possible research directions, new programs, specific grants, and policies. Others saw the oversight of the application process as their main duty and had little contact with the Institute

outside of Council. Council members emphasized openness of NIGMS staff and reported feeling uninhibited about sharing their research or policy ideas.

To identify other models, we analyzed advisory councils at five additional NIH institutes, at NSF, and at HHMI. We found that the procedures for the selection and preparation of members were largely similar across the NIH institutes, but the extent to which Councils play an advisory role varied. In some cases, Council was primarily involved in the secondary review of applications. In others, the institutes sought Council input on all important issues. NSF and HHMI used separate bodies for application review and for science/policy guidance and had more opportunities than NIGMS to take advantage of their advisors' expertise. Respondents at these organizations noted that engagement of Council required significant investment of resources. However, the efforts to substantively engage Council were seen as worthwhile, even when the proposed ideas were ultimately rejected.

Based on these findings, three courses of action are suggested to NIGMS. Specific recommendations for each option can be found in Chapter 5 of this report.

Option 1: Continue with current Council emphasis and procedures

As NIGMS Council is well run and most members and NIGMS staff are satisfied with its functioning, maintaining the status quo is a viable option. However, we suggest developing internal consensus on the appropriate use of Council and clearly communicating Council role to the members and the Institute staff.

Options 2: Increase Council efficiency without expanding its role

We identified inefficiencies in how Council members prepare for the sessions and in the format of the sessions. Council members reported that they experienced a heavy workload for each session and that sometimes they had to make arbitrary choices about which materials to review in order to manage the workload. During the meetings, significant time was used for staff presentations, which were in some cases disproportionately long relative to their importance to the Institute. Small changes in how new members are prepared for their roles and in the format of Council sessions could increase the efficiency of Council.

Option 3: Enhance Council participation in the setting of policies and scientific direction

As Council typically responds to the items brought up at the sessions, NIGMS does not take full advantage of the talent and experience of the group in setting policy and scientific direction. If the Institute wishes to engage Council more fully, we recommend refining Council role, creating venues for Council to give broader advice, and engaging Council at an earlier stage of program development.

Chapter 1: Introduction

The mission of the National Institute of General Medical Sciences (NIGMS or Institute) is to "support research that increases understanding of life processes and lays the foundation for advances in disease diagnosis, treatment, and prevention."[1] Like all other NIH Institutes, NIGMS has an advisory body. The Advisory Council (Council) has two functions: (1) to provide second level peer review of grant applications assigned to NIGMS and (2) to offer "advice and recommendations on policy and program development, program implementation, evaluation and other matters of significance to the mission and goals of NIGMS."[2] Current Council membership includes extramural scientists specializing in the areas relevant to the Institute, a public policy expert, an economist, a manager, a lawyer, and representatives from the U.S. Department of Veterans Affairs and the U.S. Department of Defense. Members are appointed for 4-year terms and meet three times a year, typically in January, May, and September. Procedures for Council formation as well as Council's composition and roles are governed by federal law and the NIGMS charter.[3,4]

At present, NIGMS staff members view the level of Council participation in advising the Institute on scientific research and policy as somewhat limited. Abt Associates was charged with examining the Council's functions to identify strategies to more effectively engage Council in this area. To accomplish this task, we posed the following research questions:

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- What are the models for engaging advisory councils at other NIH Institutes and outside of NIH? Are these models applicable to the NIGMS Council?

To answer these questions, we interviewed 38 individuals including NIGMS staff, Council members, Executive Secretaries at other NIH Institutes, and representatives from the National Science Foundation (NSF) and the Howard Hughes Medical Institute (HHMI). In addition, we analyzed a variety of existing materials describing advisory councils. Our findings are presented in this report, which begins with a description of data collection and analysis methodology in Chapter 2. In Chapter 3, we present data from interviews for each respondent group. We conclude with a

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[1]   http://www.nigms.nih.gov/About/. Accessed March 3, 2010.

[2]   http://www.nigms.nih.gov/About/Council/. Accessed February 24, 2010.

[3]   The Federal Advisory Committee Act with Amendments and Annotations. (http://www.gsa.gov/Portal/gsa/ep/contentView.do?contentType=GSA_BASIC&contentId=11635) Accessed February 24, 2010.

[4]   http://www.nigms.nih.gov/About/Council/Council+Meetings+and+Functions.htm. Accessed February 24, 2010. Accessed February 24, 2010.

summary of findings (Chapter 4) and with recommendations for actions that NIGMS might consider to more fully engage its Council (Chapter 5). In addition to the main body, this report contains an appendix that describes councils at other NIH Institutes.

Chapter 2: Methods

NIGMS provided us with a list of individuals, including senior Institute staff, Council members, Executive Secretaries at five NIH Institutes, and the initial contacts at NSF and at HHMI, to interview for this study (Table 1). To facilitate recruitment, NIGMS staff sent an email to potential interviewees informing them of the study, introducing Abt, and requesting their participation. During the Council session held in January 2010, non-responsive Council members were again encouraged by NIGMS staff to respond to interview requests.

Table 1: Interviewee Roster

Respondent Category	Number of Subjects	Number of Respondents
Staff at NIGMS	14	12
Council Members	16[a]	16
Staff at Other Institutes	5[b]	5
Staff at NSF	2[c]	2
Staff at HHMI	1	1
TOTAL	**38**	**36**

[a] 12 current members, 3 past members, and 1 ad hoc member (ad hoc member's views were excluded from the report)
[b] NIMH, NINDS, NIDDK, NHLBI, NIDCD
[c] Directorate of Social, Behavioral, and Economic Sciences

Telephone interviews were conducted by four Abt researchers from December 2009 to March 2010. At the beginning of each interview, the goals of the study were reiterated and the subjects were given assurances of confidentiality.[5] Two NIGMS staff declined to participate, citing lack of familiarity with the Advisory Council processes. The data from one Advisory Council member who was interviewed was excluded from this report, because of his ad hoc status on Council. We achieved a response rate of 95%.

The interview format was semi-structured, whereby the interviewer steered the discussion to cover a set of predetermined topics, while at the same time encouraging respondents to take the conversation into the directions he/she considered relevant to the study. The following areas were covered during the interviews:

- Preparation for Council
- Role of Council
- Processes for identifying new research directions and policies
- Communication between Council and the organization it serves

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[5] Interview protocols and procedures were approved by the Abt Associates IRB.

- Suggestions for improving Council processes at NIGMS
- Other relevant experiences

Interview data were coded with NVivo 8 software using the following codes: identification of new members; preparation for Council; roles of Council; meeting structure; research and policy guidance; communication; and criticisms, actions taken, and recommendations. The coding allowed us to aggregate the interview data by topic, facilitating synthesis and comparison across respondent categories.

Chapter 3: Findings

In this Chapter, we present the information conveyed to us during the interviews, supplemented by the review of NIGMS Council websites and the documents related to the preparation of members provided by the Institute. We conclude the Chapter with a discussion of similarities and differences in councils at five other NIH Institutes, at NSF, and at HHMI.

Information Provided by NIGMS Staff

We spoke with 12 individuals in senior positions at NIGMS, including the Institute Director, division directors, and several other key staff. While all interviewees attend Council, some were unfamiliar with certain aspects of its operations as these were outside of their job responsibilities. For example, some respondents had no knowledge of how Council members are prepared for service. Further, not all respondents attend closed sessions of Council, and therefore could not comment on what takes place there. Finally, some staff members have not been trained as scientists and were uncomfortable providing information on the contribution of Council to the setting of scientific directions. We engaged these individuals instead in the discussions of communication and social dynamics that they have observed during Council meetings (for example, we asked them whether Council members appeared interested and active at open sessions). Interview data are grouped into several topics: identification and preparation of members; Council proceedings; Council roles; engagement in policies and research directions; and communication.

Identification and preparation of members

Candidates for membership are suggested by the division staff at the request of the Institute Director and are also drawn from among the ad hoc members.[6] In addition to representation by technical area, geographic location, institution, race, and gender, NIGMS seeks individuals who are well funded, respected by the scientific community, have a broad perspective on their own field, and are able to see beyond their areas of research. NIGMS staff we interviewed reported that their suggestions regarding the candidates were considered by the leadership. They appeared to be satisfied with Council composition, although some noted that expertise in computational and clinical areas was not well represented and had to be supplemented through ad hoc membership.

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[6] *Ad hoc* members are asked to serve when a specific expertise is missing from Council, or if a regular member has a conflict of interest or is unable attend the meeting.

By law, several slots on Council must be filled by social scientists or lay members—economists, lawyers, and management experts. For the economist slot, the Institute looks for individuals whose research overlaps with NIGMS areas; lawyers and managers are typically recruited from among former scientists who have transitioned into law or university administration. We were told that appointments to Council were to some extent political. Under the previous Bush-Cheney administration, Council members were sometimes suggested to the Institute, not always appropriately.[7] Our interviews revealed that it could be difficult to engage the entire Council, in particular on technical matters, because the Council composition is very diverse—from basic chemists to clinicians to non-scientists. Council members tend to be more active in the discussion of policy matters, for instance, training or funding for large-scale science projects.

The Institute uses various mechanisms to prepare new members for service. Freshmen (as well as serving members) receive three documents: (1) instructions on how to use the secure council website; (2) instructions on how to use the Electronic Council Book; and (3) a guide on what to expect from the meeting. In addition, the Executive Secretary briefs all new members by telephone, going over the use of the electronic sources as well as discussing Council responsibilities. This briefing takes about an hour. Finally, if needed, new and ad hoc members meet with NIGMS staff the morning of the first session.[8]

In addition to the documents provided to the members, information related to Council can be found on the NIGMS Council websites.[9,10] The top hit on Google.com (using "NIGMS council" as a query) is a website that contains extensive information on Council responsibilities , policies, and activities. The second hit is a link to another webpage, with an embedded Council roster, meeting dates, most recent agenda, meeting minutes, presentations, and other items. We noticed that a strong emphasis is placed on the peer review function over advice on policy and science. For example, the NIGMS Council Information website is almost entirely devoted to the secondary review of applications. Council's role in policy-related advice is described in one paragraph and there is no discussion of its role in the setting of research directions. In our view, between the documentation provided to Council and the websites, sufficient information is easily available to understand the role of Council role and to envision how the proceedings are structured.

NIGMS staff acknowledged in the interviews that despite the efforts made by the Institute to prepare new members, the first meeting could still be overwhelming for new Council members:

> *The first Council meeting is always a battle because they really do not know what the process is and they are a bit shy…*[11]

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[7]   NIGMS resisted these appointments to the extent possible (interview with an Advisory Council member).

[8]   Council Game Plan: What to expect and when (May 2009). Internal NIGMS document.

[9]   http://www.nigms.nih.gov/About/Council/. Accessed February 25, 2010.

[10] http://council.nigms.nih.gov/general_info/orientation.html#get. Accessed February 25, 2010.

[11] The interviews were not recorded, therefore quotations may not represent the exact wording.

The adjustment process is easier for individuals who have served as ad hoc Council members or as NIH reviewers and more difficult for lay members unfamiliar with the NIH culture and language. According to the staff, the key challenge for new Council members is not to understand what happens at Council, but to learn how to prioritize the enormous amount of documentation – hundreds of pages—that they receive prior to each meeting. Some NIGMS respondents noted that they should find a solution for helping Council members manage the workload, but expressed reluctance to providing very specific guidance (such as telling them what they should read in preparation for the meeting). Respondents believed that after the first meeting, new members should know what to expect.

Council proceedings

NIGMS Council meets three times a year over a day and a half. The first day is devoted to the discussion of applications, appeals, merit extensions, and other items that require second-level peer review. These activities take place in two closed sessions. During the first closed session, Council breaks out into three groups, for the divisions of Cell Biology and Biophysics, Genetics and Developmental Biology, and Pharmacology, Physiology and Biological Chemistry. Decisions made in these subgroups are reported back to full Council. Any issues related to the Minority Opportunities in Research Division (MORE), the Center for Bioinformatics and Computational Biology, and Training programs, are also discussed in closed session. In addition, programs projects and centers are considered individually.

The second day is open to the public and includes the NIGMS Director's updates on the Institute and NIH-wide matters as well as presentations by NIGMS staff on concept clearance, program evaluation, training and diversity initiatives, and other topics. Speakers from outside of NIH, including Council members, are often invited to give scientific or policy talks. During the open session, the dates for future sessions are confirmed.[12] The last segment of the open session is allocated to a Council-initiated discussion.

Roles of council

NIGMS staff members were in agreement that the second level of grant application review is the priority for Council and that this function should not be compromised by expanding its advisory role. In contrast, there was a divergence of opinion on whether, and to what extent, to involve Council in providing advice on policies and scientific directions. The staff appeared to be aware of these differences and noted that they should reach a consensus internally on "what amount of input is necessary and appropriate." A common opinion expressed was that Council is more effective in providing advice on policy—for example on training, minority programs, or large initiatives—than on science. Respondents who held this view believed that while Council members have a broad range of expertise, it is not comprehensive, and therefore expert panels are preferable for advising the Institute in specific scientific areas (these panels may include Council members with relevant expertise). Another point was made that it is difficult to engage Council in setting research direction

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[12]   http://www.nigms.nih.gov/About/Council/Agenda/. Accessed February 24, 2010. Accessed February 24, 2010.

because members "do not understand the context," lacking knowledge, for example, of other NIGMS grants funded in various portfolios or of the research funded by other Institutes at NIH.

Other respondents seemed to be in favor of engaging Council more fully both in policy and in science:

> *Council should be saying "this is an exciting area" or" the community is struggling with this policy" to try to give [NIGMS] a sense of things that are not on our radar as much as they should be.*

> *Council focuses on minor issues and that consumes all their time. We should use Council for more important discussions—what are the trends in science and what should NIGMS fund—and this would make the meeting more worthwhile.*

Finally, while acknowledging that Council was not particularly active in an advisory capacity, some respondents expressed a view that the current level of participation was appropriate and that no change is necessary:

> *There aren't any issues raised…. Maybe there aren't any smoldering issues that the Council needs to raise. Maybe GM is on top of most of the issues…. Things are not dramatically out of balance.*

> *The Council role is basically appropriate.*

Regardless of their position on the appropriate role of Council, the majority of NIGMS staff felt that Council was not fully engaged and that the Institute was not taking advantage of the talent and knowledge that Council has to offer. We were also told that the Institute has streamlined some of its functions in order to use Council time more strategically. For example, Council no longer reviews budget appeals and unscored grants. NIGMS staff strongly emphasized that it is not their intent to use Council as a "rubber stamp" and expressed hope that Council members view their contribution to the Institute as meaningful and worthwhile.

Engagement in policies and research directions

While much of Council's time is taken up by application review, there are nevertheless several opportunities to give broader advice. One venue is the breakout sessions where the members discuss grant applications and appeals. Several respondents noted that the intimate atmosphere of breakout sessions is more conducive to a meaningful discussion, and therefore the divisions with breakout sessions are more likely to receive direct input from Council. However, it emerged that while Council members do sometimes make brief comments on the proposed research, in-depth discussions of science are rare. Concept clearance is another venue for Council members to offer scientific guidance, but in practice concepts are typically (but not always) approved with few revisions. We were told that program concepts undergo several rounds of review by NIGMS and are usually well formed by the time they are presented to Council. Finally, the agenda includes time for a Council-initiated discussion, but the members rarely take advantage of this opportunity.

During the interviews, we asked respondents to provide a recent example of a suggestion related to policy or research direction that had been introduced by Council and adopted by the Institute. Of 12 respondents, five could not think of any examples. Those who provided examples spoke about Council contributions to the discussions of large grants (e.g., the Protein Structure Initiative), funding for international investigators, the NIH peer review process, training programs, and diversity initiatives. In these examples, Council views were always seriously considered, but may or may not have been ultimately adopted by the Institute.

Interviewees said that some activities appeared to engage Council more than others. Presentations by the NIGMS Director, reports from expert panels, and scientific talks tended to stimulate discussions. For example, Council was very active during the development of the Institute's Strategic Plan and during the presentations on the Roadmap programs. In contrast, Council members seemed less interested in some of the talks given by program staff. Respondents felt that sometimes these presentations covered too much detail and were disproportionally long relative to their importance to NIGMS.

Several NIGMS respondents spoke of the challenge of engaging Council beyond their primary function of application review. As NIGMS receives a very heavy load of applications and appeals, much of Council's time and energy is taken up by the review. Council members have more opportunities to give science and policy advice during the open session, which takes place on the second day. (The open session had to be moved from the first day because of scheduling challenges and concerns that application review was not getting sufficient Council time.) One respondent made a point that circumstances beyond the Institute's control may have an effect on the level of Council engagement. For example, during flat budget years, there was little enthusiasm from Council in steering research because of the lack of funds. The Recovery Act funds presented their own set of challenges, with timelines being too short to obtain substantive Council input.

Communication

According to NIGMS staff, an extensive exchange of information occurs between Council and the Institute. First, Council members are provided with documentation prior to the meetings, and new members are debriefed by telephone and in person. Second, senior staff members (and most professional staff) attend Council meetings. Third, all major decisions made in subgroups are brought back to full Council. Finally, minutes taken during the open session are posted on the Council website (meeting minutes going back to 1997 are available).[13]

We examined the open session minutes from the last Council (January 22, 2010).[14] The summary, posted just a few days after the meeting, contained one-paragraph descriptions of each presentation made during the open session. We noticed that two of the items in the minutes clearly indicated Council engagement. One was a presentation by a Council member, who reported on the review of the NIGMS-supported synchrotron facilities conducted by the Council working group. Also of note was a summary of concept clearance, which stated that Council recommended revising the

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[13] http://www.nigms.nih.gov/About/Council/Minutes/. Accessed February 26, 2010.

[14] http://www.nigms.nih.gov/About/Council/Minutes/jan21-22_2010.htm. Accessed February 26, 2010.

scope of the solicitation. The minutes described three policy-oriented talks, on broadening participation of individuals with disabilities, on the support of young investigators by NIH, and on processes for strategic planning in training. No information was included on the content of Council-initiated discussion.

NIGMS and Council members also communicate between meetings. The Executive Secretary, in particular, is in frequent contact with the members, and other NIGMS staff members reach out to Council if the need arises. For example, interviewees mentioned teleconferences and email exchanges between Council and NIGMS on issues related to the working group on training. Sometimes NIGMS gives advance notice to individual members or to groups of members on the topics planned for the next session and encourages Council to raise any concerns at the session. Any issues brought up by Council are discussed at biweekly senior staff meetings and updates are provided at the next Council or sooner on the actions taken in response to Council recommendations.

Based on NIGMS staff input, we identified two communication gaps. First, some staff members were uncertain what level and nature of interaction between staff and Council outside of the sessions were considered acceptable by the Institute. Second, one respondent expressed a view that Council proceedings might be perceived differently by observers, but that there was no mechanism to reconcile what staff members took away from Council. Note that according to NIGMS, staff members and Council receive a confidential document describing Council recommendations and actions planned by the Institute. We are uncertain why the respondent held this view.

Information Provided by Council Members

In this section, we present the opinions expressed by 15 Council members. Most respondents were very engaged in the discussion and candid about their experiences. Information collected during the interviews is organized into five topics: preparation for Council, role of Council, engagement in policies and research directions, communication, and satisfaction with Council. The following expresses the views of Council members in their own voice, using extensive quotation in summarizing the data.

Preparation for Council

Most members recalled receiving a variety of materials and being briefed by NIGMS staff. While respondents found the information generally clear (except for one lay member who struggled with terminology), it did not completely prepare them for what actually occurs at Council.

> *The information provided was very procedural in the sense of what types of resources were available, summary statements, and issues that have to be resolved by the Council, such as conflicts and appeals. No information was given about what the expectations were other than to provide NIGMS with advice when requested. I thought we were going to discuss scientific directions; however in reality there was more discussion of procedures (e.g. how to terminate large programs).*

The information was clear, but it did not reflect exactly what is going on at the meetings.

Respondents noted that NIGMS staff told them that they would learn about their responsibilities through participation and encouraged them to speak to other Council members; these consultations were described as valuable.

The most important thing that they told us is that one learns as one does this. They advised us to look at what the most senior (experienced) members are doing as well as to solicit advice from them.

The previous Council member talked to me about what he did, what was most important, what was possible, and what the issues were with Council, which I found to be very helpful.

The key challenge identified by Council members was managing an enormous workload of materials provided by NIGMS. We were told that hundreds of pages of assignments were given on short notice, that the load was unpredictable, and that no direction was offered on what to focus on or what level of preparation was adequate. Note that some division directors did offer guidance when asked for it. Respondents wished that NIGMS was more explicit on how to approach the enormous volume of work.

At the last meeting I had 800 documents that were 5-20 pages each and 3 weeks' notice and I am already in a full-time job. You have to figure out what needs your attention and they will point you to some of that, but you have to use your judgment. Talking with other Council members was helpful for that. I did not get a whole lot of guidance from NIGMS staff.

There is a great deal of information to review before each meeting and there is a concern that some time is wasted sifting through this information. It would be helpful if Council members received more guidance for prioritizing tasks and obligations to determine what is most relevant.

A few respondents found using the Electronic Council Book somewhat challenging at first, but soon became comfortable with this tool. In general, most Council members said that after a few meetings they were "up to speed" on Council functions. Finally, Council members reported that any information requested from NIGMS has always been provided promptly.

Engagement in policies and research directions

Roughly half of Council members (7 out of 15 or 47%) identified two Council roles: (1) secondary review of applications and (2) assisting the Institute in identifying general directions and policy making. Another five (33%) said that Council was mainly responsible for second level review. The remaining three (20%) could not give a clear answer when asked about Council roles. The quotes below are representative of respondent comments:

There are two functions. The first is its role as a second filter to determine if the review of applications was conducted properly. The second function is to advise the Institute Director on new scientific initiatives.

The principal role is to provide some authoritative backing to the NIGMS folks when they have to make decisions about borderline grants or other project grants, so when someone protests their score, NIGMS can cite professional Council. We've got their back, so to speak.

While half of Council members were aware that one of their roles was advising the Institute on science and policy, almost all said that in practice it rarely happens. Many respondents did not consider this type of guidance as a primary function of Council. We were told repeatedly that Council responded to what NIGMS staff presented to them, and that its role was largely reactive. All or most of the scientific ideas and new policies were developed by the Institute.

Historically, this [identification and development of ideas] *is not something that they have really done. NIGMS staff makes a presentation at meeting to say why they think something is important and then the Council votes on it. There may be some individual examples when Council members speak to NIGMS staff about an idea, but generally it's the staff.*

Collectively as a Council there is very little of this kind of identification. Generally, this is done on an individual basis.

This is certainly verbalized, and I think GM is interested, but I don't see it happening very much in the current context.

Many respondents commented that Council has extensive expertise and could be used more substantively for guidance.

This is a missed opportunity. A lot of people in that room could contribute scientifically, but it is not being utilized.

They use us as a sounding board. We could probably do more and they could use us in a more proactive way.

I am amazed by the people who are at these Council meetings and their backgrounds, expertise, and the contributions they can make. There should be a better way of picking their brains in a more proactive way than reactive. Currently most of what we do is reactive. There are limits to the kinds of responses that you can get in a reactive situation, because unless someone feels strongly about it, there is a tendency to be quiet.

Interviewees noted that the agendas for the meetings were already full, and there was little time left for Council to be more proactive. If NIGMS staff were interested in Council's scientific guidance, they should explicitly ask the members to think about the Institute's portfolio and then provide a venue to discuss various ideas. For example, several years ago, NIGMS sponsored a workshop, "Visions of the Future," where researchers from different disciplines were asked what the future

might hold. According to respondents, an event such as this could be a good mechanism for Council to identify promising areas of science.

Several respondents were critical of the concept clearance process. They pointed out that by the time Council was asked for input, NIGMS staff had "committed emotionally" to the idea, and Council members were uncomfortable expressing frank opinions. Therefore, they believed that Council was not being used in an advisory role.

The minority view (expressed by three respondents) was that Council should not be directive in the areas of science. Three arguments were made in defense of this position. First, most of the scientific research funded by NIH is investigator-initiated and should remain as such. While Council members must ensure that the best research gets funded, it is not their role to steer the Institute:

> *Scientists themselves have the best ideas. While we can be suggesting new initiatives that might encourage people to think along certain lines, the primary driver is initiative of investigators as evaluated by peer review.*

Second, some respondents believed that it could be "dangerous" for Council to be more proactive. As most of the members are NIGMS-funded scientists, their advocacy for scientific areas of focus would risk creating a conflict of interest. Finally, Council members represent very different scientific fields, so it would be very difficult for them as a group to reach a consensus on a priority list of areas, even if NIGMS organized an event exclusively for this purpose.

The interviews also revealed that the level of engagement beyond secondary review of applications varied depending on the commitment and interest of Council members. It was clear that some members decided to use Council to influence policy. For example, one individual identified several items of concern on which he wanted to focus during his tenure, such as new investigator and minority support. This individual has taken every opportunity to contribute in these areas, through participation on committees, direct conversations with relevant Institute staff, and other activities.

The interviewees stated that occasionally the whole Council or a group of members became engaged in some issue. This happened, for example, when a new scoring system for grant applications was relayed to Council. In reaction, several members mobilized to write a letter to the Institute Director presenting their concerns with this important policy change. Similarly, a Council member might have a very clear vision for a specific line of research that the Institute should pursue. This individual would take on a leadership role, reaching out to other members, and advancing the idea with the Institute. For example, we were told that a few Council members have been talking to NIGMS staff about possible research directions in the area of drug safety. The members plan to ask the Institute to put together a conference on this topic. Another respondent mentioned that several Council members have begun a discussion with NIGMS staff over lunch about a research idea. This lunch has been followed up with a conference call and with additional lunches during subsequent Councils; that conversation is still in process.

We asked the members to think of a specific example of Council advice in the areas of policy or science. Almost all respondents were able to do so, although sometimes they did not know whether the advice has been taken by NIGMS. Examples of Council input were as follows:

Policy
- Council members noticed that in some cases proposals from assistant professors have been triaged three times without a review. The members believed that all assistant professors should receive at least one substantive review after the first submission, the view they communicated to NIGMS leadership. The respondent thought that the policy had been put into effect, but was uncertain to what extent the change was due to Council intervention (example from one Council member).
- Council became concerned with the new scoring system. The members developed a memo that conveyed their views and sent it to the NIGMS Director last November. Respondents did not know whether the Institute had taken any steps in reaction to the memo[15] (example from three Council members).
- Council examined MORE initiatives and suggested several changes, which have been adopted (example from four Council members).
- A member collected input from Council on training and organized it into a report. There was a discussion in full Council that followed (example from one Council member).
- Council challenged the policy which limited one supplement per parent grant to support a student from a group typically underrepresented in biomedical research. The policy has been changed so that more than one student can be supported on an R01 grant (example from one Council member).

Science
- Council members felt that the research community has not been adequately consulted on the Protein Structure Initiative, resulting in the omission of important scientific areas. Council proposed greater outreach to the community to fine-tune the Initiative. Council members believed that NIGMS responded, and were satisfied with the outcome of their intervention; one respondent wished there were more opportunities like this for Council (example from three Council members).
- Council members played a role in shaping the Glue Grants program. In response to Council concerns, NIGMS enhanced the oversight of the program, and later revised it incorporating suggestions from Council (example from two Council members).
- At the most recent meeting, Council reacted negatively to the Multivalent Agents concept and requested revisions (example from two Council members).

Communication

In the interviews, we asked respondents several questions related to communication with the Institute. All respondents were in agreement that NIGMS promoted openness and that they were comfortable contacting NIGMS staff or even the Institute Director, if the idea or concern was important. One respondent said that Council members were encouraged by the Institute to think of research or policy ideas and to bring them up for discussion during Council or between the sessions.

There are several venues for communication between Council and the Institute. Council members contact NIGMS staff, usually division directors, between the meetings. In some cases, NIGMS staff

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[15] NIGMS forwarded the memo to the NIH leadership (NIGMS, personal communication).

solicits input or guidance from the members, sometimes on issues unrelated to Council business. Council members also communicate with each other outside of the sessions. For example, one member remained silent during Council, but a few days later circulated a memo summarizing various viewpoints expressed at Council and presenting his own opinion. Exchanges unrelated to Council also take place between the members.

While many respondents did not feel inhibited in expressing their views on a policy or a research area to the Institute, they noted that there was no effective venue for such discussions during the sessions. Council-initiated discussion, the item on the agenda meant for this purpose, is scheduled for the very end of the session, when the members are tired and ready to depart. Two council members said that they would appreciate more unfettered access to the Institute Director, for example during the lunch break. A private discussion, without all of the staff in attendance, could be a good venue to broach new ideas. Other opportunities for interacting with NIGMS staff informally were also suggested, such as dinner[16] or "muffins in the hallway."

We asked Council members whether NIGMS updated them on the status of items discussed during the session. We were told that Council was quickly notified if an action had been taken, but might not be provided with an update if the Institute decided against their recommendation. However, at least one respondent expressed the view that Council advice "does not fall on deaf ears," even if, understandably, the Institute did not always take their advice.

> *If they don't take our advice, that's fine. We are only there a few days a year and they work full-time trying to figure out how to support the community.*

Satisfaction with Council

Of the 15 Council members interviewed, four expressed strong satisfaction, 9 expressed satisfaction, and two were unsatisfied with Council. Below are the examples of respondents' positive views:

> *I have found it to be really stimulating. It is hard work, but not drudgery. It's very illuminating. Sometimes it's frustrating to see them put a lot of money into an initiative that we do not support and we may disagree, but that's fine. Overall I've found it to be much more rewarding than serving on study sections, which is more like a service. Being on the Council is more like a privilege.*

> *It's been one of the most unique opportunities in my career. You become myopic working in one specific field and lose awareness of other areas, but in Council you become rapidly familiar with what's going on in other fields including emerging fields, what other people are doing, and how it applies to the work I am doing.*

> *It is a very well run Council.*

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[16] NIGMS used to have dinner after the first day; this practice was cancelled due to lack of staff interest in attending (NIGMS staff interview).

Almost all Council members, regardless of their level of satisfaction, would have preferred to have greater involvement and impact in substantive areas.

> *I like it. It makes me appreciate how difficult it is to run NIGMS. I would be more satisfied if we discussed science more. Other than that, it is a great group of people. The staff is unbelievably responsive and Jeremy is the glue that holds it together. It would be nice to give Jeremy an opportunity to take advantage of our combined scientific expertise.*

Of the two individuals who appeared unsatisfied, one said that NIGMS staff were "doing a wonderful job, but the confines of how the government has to cover all these things unrelated to science makes it impossible to think of science."

Other Models of Advisory Bodies

To examine other models of advisory bodies, we interviewed knowledgeable staff at five NIH Institutes (NHLBI, NIDDK, NIMH, NINDS, NIDCD), at the National Science Foundation (NSF) (Division of Social, Behavioral, and Economic Sciences or SBE), and at the Howard Hughes Medical Institute (HHMI). Since Councils at NIH are governed by federal law, many of the policies and procedures were similar across the Institutes. To avoid repetition, we present a summary of the processes of selection, preparation, and engagement of advisory councils at NIH. Detailed profiles for each Council are included in the appendix. In contrast, advisory bodies at NSF and HHMI were quite different from the NIH Councils and we describe them individually in this section. Table 2 in the end of the section is a summary of the operating procedures for various advisory bodies. Data on how five NIH Institutes use their councils are presented in the Appendix.

As the identity of respondents at the five Institutes is known to NIGMS and we interviewed one individual per Institute, reporting of the data by Institute will link respondents' identities to the specific information they provided. To avoid violating confidentiality of the answers, we refer to the Institutes as Institutes 1–5.

Advisory Councils at Other NIH Institutes

Unlike NIGMS, the missions of the five Institutes investigated for this report are focused on specific human diseases and conditions. This difference is relevant to the Advisory Council functions for two reasons. First, the NIGMS Council might have to include a broader range of technical expertise than Councils at more narrowly focused disease-oriented Institutes. Second, because the mission of NIGMS is less clearly defined, it is particularly important for Council members to understand what scientific niche the Institute occupies within NIH; Council members are unlikely to have that knowledge. Several respondents pointed out these differences to us, and predicted that engaging the Advisory Council at NIGMS in defining scientific directions could be challenging.
We observed both similarities and differences in how Councils at other Institutes are managed. Processes related to the identification of new members appeared to be quite similar. In all cases, nominations come primarily from staff; all Institutes look for established researchers who are broad thinkers. Lay members are generally recruited from among formerly active scientists who have transitioned into university administration, law, or journalism and from advocacy organizations

focusing on relevant diseases. Final decisions on the membership are made by the Department of Health and Human Services.

Procedures related to the preparation of new members for service are somewhat different. Some Institutes invite freshmen to a Council session preceding their formal tenure. At other Institutes, new members attend an orientation session the day before the meeting, or are instructed by telephone or a videocast. One of the Institutes has begun conducting interviews with new members, to determine their level of satisfaction with Council procedures.

The extent to which Councils play an advisory role varies by Institute. Institute 5 emerged as a strong believer that Council's time is too valuable to be used exclusively for secondary review. Similarly, Institute 4 took steps to energize its Council in the advisory role by soliciting direct input from the members on their interests. At Institute 2, in contrast, grant and initiative reviews are seen as the primary functions of Council. Institutes 1 and 3 are somewhat in between.

While the level of Council engagement varies, the mechanisms used by the Institutes to solicit Council views are similar. Discussions of polices and scientific matters typically occur during grant review, concept clearance, and presentations by the Institute's staff in open sessions. In addition, Council members are often recruited for working groups charged with identifying new research areas that the Institutes are considering. All Institutes provide some feedback from the sessions to their Councils, but the extent of communication between the sessions and the level of formality varies. At Institute 4, for example, all communication between the Institute and the Council takes place through the Executive Secretary. At Institute 1, there is little communication with Council between the sessions.

Advisory Bodies Outside of NIH

In contrast to NIH, advisory councils at NSF and HHMI are not governed by federal law and, therefore, these organizations have significant flexibility in how they use their advisory bodies. We were fortunate to be able to speak with individuals managing advisory bodies at NSF and at HHMI who were also familiar with NIH Councils (the HHMI respondent was actually a Council member at one of the institutes). As a result, they were able to draw meaningful comparisons between NIH and their organizations.

National Science Foundation Directorate of Social, Behavioral, and Economic Sciences (NSF SBE)

Candidacies for the Advisory Committee (Committee) are discussed between the current members, especially the chair, and the NSF staff, and the final decision lies with the assistant director of SBE. Most of the Advisory Committees at NSF are composed of 15–20 members, depending on the scope of their activity. The SBE Committee currently includes 18 members.[17] At SBE, a very broad range of disciplines is embedded within the directorate and the Committee cannot be entirely representative, but staff makes an effort to get as much coverage of the subjects as possible. In

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[17]   http://www.nsf.gov/sbe/advmembers.jsp. Accessed March 4, 2010.

addition, NSF tries to balance the membership by gender, ethnicity, geography, and types of employing institutions. There is no requirement for lay members and at the moment every member of the SBE Committee is an academic researcher. Most members serve for three years, although in some instances the tenure is extended. The Committee meets twice a year, in the Fall and in the Spring, for a day and a half.

Most of the directorates at NSF provide some form of brief orientation, usually conducted immediately before the first meeting; at SBE the assistant director speaks with new members in the early morning of the first day. The directorate also uses a restricted website. The documents on which NSF is soliciting the Committee's input remain on the restricted website until the decision is made.

The main function of the SBE Committee is to provide science and policy advice to the staff and the assistant director. The Committee plays no role in the secondary review of applications to NSF. The proceedings are a mix of plenary discussions and breakout sessions. SBE has three divisions and the Committee is segregated into three parallel 2-hour sessions, where the members meet with the division staff to learn about their activities and to give feedback. Breakout sessions are used to focus on specific scientific issues. Occasionally, an assistant director from another directorate is invited to participate in the Committee meeting, usually to initiate a discussion on collaboration. In addition to input on the areas already funded by the divisions, the directorate is looking to the Committee for guidance on the scientific areas where NSF should become a more influential player. Finally, the Committee participates in program reviews that occur every three years.

As the respondent only recently joined NSF, he has not yet personally engaged the Committee in the discussion of scientific issues. He has considered how to do it, however, and is planning to prepare a brief white paper to set off a discussion, possibly developed in parallel by NSF and by the Committee. While new to this position, the respondent has led an international consortium of universities which had an advisory body, and he has drawn upon this experience. The respondent suggested that it is always worthwhile to hear advice, even if he disagrees with it. He also said that if the advice were periodically taken, the members gradually would begin giving serious attention to the issues. He emphasized the need to report back to the advisory body on the actions taken, including when the decision has been made not to follow a recommendation. In the respondent's experience, "the more responsibility you give them, the better they perform."

The respondent also noted that advisory committee members tend to feel most comfortable talking about the areas that they know best and sometimes it is difficult to steer them to the discussion of "the big picture." Therefore, it is important to ground the discussion and to reiterate that their role is to think about the future of science.

Finally, the interviewee made a point that it takes a significant time commitment to effectively engage advisory bodies. In his old position, for example, he and his management team of 10 spent some time over the course of the whole year to resolve the issues raised by the council and to prepare for the meetings. If NIGMS is considering engaging Council more fully, the respondent recommended carving out a short time slot to deal with a specific small issue first, thereby gradually accustoming Council to this role.

Howard Hughes Medical Institute

Three groups oversee the Howard Hughes activities: the Trustees, the Medical Advisory Board (MAB), and the Scientific Review Board (SRB). According to the respondent, the Trustees are presented with "a 30,000 feet view of HHMI"; this group does not correspond to an NIH Council, which resembles a mixture of MAB and SRB. The SRB reviews applications and renewals and the MAB is a guiding body.

The MAB meets for half a day four times a year and is composed of approximately 10 individuals, all established scientists. They serve three-year terms and can be reappointed. Decisions on the membership are made by HHMI. Members of the Medical Advisory Board are often former Hughes investigators, and are familiar with the organization by the time they are asked to serve. To prepare new members, HHMI holds a one-day orientation where the roles of the Boards are discussed. New members are also provided with background materials about HHMI.

One of the roles of the MAB is to be the first sounding board for new programs HHMI staff is considering. The respondent said that the ideas put forth by staff have "taken some shape and form, but are not done deals." While the advisory board is notified about the initiatives at a relatively early stage, the respondent was clear that it is not the role of the Board to micromanage the organization.

The interviewee was sensitive to the challenges of substantively engaging advisory bodies. He noted that because council meetings are infrequent and brief, there is a temptation to "bring them the cake which is fully baked and to have them light the candles." It is difficult to have a discussion about science direction or the future of training programs when a council is restricted by time. The cake analogy used to apply to the HHMI Medical Advisory Board, but at some point, the Foundation made the decision to engage the MAB more fully. As a venue for this engagement, HHMI began holding two-day retreats every two years, which are devoted entirely to the discussion of big-picture issues in policy and science. All MAB members are invited, along with the HHMI president, vice presidents, and the budget officers. The respondent noted that the utility of the retreats is not only in allowing sufficient time to talk about new directions, it is in providing a venue for the foundation management to hear what the organization is doing. HHMI develops a structured agenda for the retreat, which is shared. The respondent noted that if an issue is controversial but known in advance, it is easier to reach consensus at the meeting. To identify potential differences of opinion, MAB members are asked for feedback on the agenda.

The respondent offered two examples of substantive contributions by the Medical Advisory Board. A few years ago, HHMI staff decided to change the application process, from nominations by the institution to self-nomination, a radical change for the organization. This proposal was extensively discussed during the retreat, with all pros and cons and half-way measures considered. Ultimately, HHMI converted to the new system in the next competition, which turned out to be the right choice for the foundation. In another example, the Board suggested that research on plants was underfunded in the United States and that HHMI should expand into this area. In response, HHMI convened a one-day symposium of researchers in plant biology. The decision has been made to

support plant biology and a small grant competition is planned. The Medical Advisory Board is updated on the actions taken or not taken by HHMI. If a recommendation is not taken, the reasons for this decision are discussed with the Board.

Like the NSF respondent, the officer at HHMI said that engaging an advisory body takes commitment and energy. He noted that the retreats are a particularly appropriate venue, as they offer an opportunity to focus exclusively on big issues.

In conclusion, it emerged from speaking with managers of various advisory bodies that more active engagement of participants is worthwhile, but does not come about organically. The organizations have made a decision to use their advisors more fully, invested time and effort in the groundwork, and developed special mechanisms to facilitate higher level input.

Table 2: Operating Procedures for Other Advisory Bodies

	Identification of members	Preparation for service	Roles	Engagement in science & policy	Communication
Institute 1	• through Institute divisions and professional organizations • through advocacy organizations	• internal documents • phone briefing • attending Council prior to tenure	• secondary review of grants • advice on science and policy	• concept clearance • membership on the Board of External Experts • analysis of the Institute portfolio	• little communication between sessions • interviews with new and retiring members
Institute 2	• primarily through the Institute • occasionally through professional societies and Council members	• internal documents • orientation session the day before	• primarily program and proposal review	• Executive Secretary is in close contact with Council • *ad hoc* reporting to Council	• meeting minutes or brief emails to Council
Institute 3	• through Institute divisions	• internal documents • presentation by director the day before Council	• secondary review of grants • advice on science and policy	• concept clearance • expert panels • scientific presentations	• report by Director and Executive Secretary • occasional communication between sessions
Institute 4	• through the Institute • through reviewers, advocacy groups, alumni Council members	• internal documents • introduction by video-link • in-person orientation	• secondary review of grants • advice on science and policy	• during open sessions • through *ad hoc* working groups	• during the meeting • at dinner • via email
Institute 5	• through the Institute • through advocacy groups	• internal documents • 2-hour in-person orientation	• Council is involved in all important issues	• concept clearance • review of applications received for FOAs • involvement in strategic planning • scientific workshops	• proposal review • presentations on budgets and policy issues • intramural activities review • participation in strategic planning
NSF SBE	• proposed by current Committee, final decision by assistant director	• orientation before first meeting • restricted website	• science and policy advice	• at meeting twice a year	• respondent is new to NSF, but plans to provide brief reports
HHMI MAB	• by HHMI staff	• one-day orientation • documents about HHMI and their roles	• science and policy advice	• during MAB meetings • during a retreat every two years	• discussion at the next meeting

Chapter 4: Conclusions

In this Chapter, we present answers to the study questions posed in the beginning of this report.

How are Council members identified and prepared for service? What information and materials would Council members find useful to prepare them for service?

At NIGMS, candidates for Council are proposed by the staff and the composition of Council is satisfactory to the NIGMS community. New members are provided with a variety of materials describing Council roles and activities; information about Council is also posted on NIGMS websites and is easily accessible through search engines. In addition, freshmen are briefed by the Institute on the phone and in person. In our review of NIGMS sources, we noticed a strong emphasis on the peer review function over the role of providing science and policy advice.

Despite the availability of these materials, many Council members reported being unprepared for what actually took place in their first meeting. The biggest challenge identified both by the members and by NIGMS staff was in the amount of material that Council is asked to review before each session. It was clear that new members (and some standing members) needed guidance on how to manage the workload. NIGMS staff was aware that Council members might be overwhelmed by the assignments, but expressed some reluctance to offer explicit advice to avoid biasing Council. Individual division directors do provide this type of guidance when asked for it.

Is there a clear understanding among Council members and NIGMS staff about Council roles and responsibilities?

Roughly half of Council members identified secondary review of applications and general advice on policy and science as two roles of Council; another third said that their main role was the secondary review. At the same time, almost all Council members noted that their role in guiding the Institute was largely reactive to the ideas proposed by NIGMS. While individuals or subsets of members do provide occasional advice on specific topics (through working groups, for example), as a group Council is rarely, if at all, used in the advisory capacity. Council members overwhelmingly reported that their expertise was underutilized and that if NIGMS was interested in using them as advisors on science, they should emphasize this role and provide a mechanism for this type of input. While many Council members wished to be more engaged in science discussion, almost all (87%) expressed satisfaction with their service.

We also noticed a lack of consensus among NIGMS staff on how to use Council. Some respondents thought that Council was more effective in policy rather than science advice; others advocated for greater engagement in policy and in science; yet others were satisfied with the status quo. Several NIGMS staff told us that there was a need for an internal discussion on the appropriate use of Council. Regardless of their position on Council roles, NIGMS staff valued Council input and hoped that the members saw their service as productive and meaningful. Both Council members and NIGMS staff viewed application review as the top priority for Council, and a role that must not be compromised.

What processes and procedures are in place to facilitate Council's advisory role to NIGMS on matters of science and policy? How can these be changed to engage Council more fully and more systematically?

In theory, there are several venues for Council to offer general advice: during the grant reviews, during concept clearance and other policy and science presentations, and during Council-initiated discussion. In practice, input from Council is limited and largely reactive, in particular in the area of science. Several Council members singled out the concept clearance process as flawed, noting that the Institute had already committed to the idea by the time it was presented to them for approval. Council appeared to be somewhat more active in the policy arena, in particular in the areas that were consequential to their own professional lives, such as training or peer review. We also found that NIGMS does seek more proactive advice from Council on an individual or small group basis, sometimes in areas unrelated to Council business. Council members participate in workshops, expert panels, and other similar activities aimed at soliciting science advice when their background is appropriate. Some NIGMS respondents expressed a preference for these types of venues in soliciting advice on the direction of science.

NIGMS staff observed that some activities engaged Council more than others. The Director's report, for example, or scientific talks appeared to be of interest to Council. In contrast, presentations by NIGMS staff were characterized as too long relative to their importance. Respondents made a number of suggestions on how to engage Council more fully; these are presented below.

Are there any areas of communication between Council and NIGMS staff that need to be enhanced?

The notion of openness articulated by the Institute during the interviews has clearly reached Council members, who appeared uninhibited in contacting NIGMS staff, including the Institute Director. However, we identified a few gaps both in the internal communication and in the communication between NIGMS and Council. It emerged from the interviews that some NIGMS staff lacked clarity on the appropriate level of communication between the Institute and the staff. It was clear that if NIGMS wishes to engage Council more proactively in giving policy and science advice, this role has to be explicitly communicated, because Council members did not think that NIGMS is looking for this type of input. Furthermore, the Council schedule is already too full and the current format of the proceedings is not conducive to the in-depth discussion of science directions.

What are the models for engaging advisory councils at other NIH Institutes and outside of NIH? Are these models applicable to the NIGMS Council?

Two themes emerged from our analysis of other advisory bodies. First, greater engagement will require greater investment of time and effort. For example, NSF staff plan to develop a white paper to ground a discussion of scientific areas. However, we also found that the organizations that did take the step of using their advisory bodies more fully reported that the effort was worthwhile as "greater responsibility led to better performance" of their councils. Institute 4, for example, took steps to make Council more active, with no regrets from the staff. This view was echoed by NSF and HHMI, who said that advisory council input was always valuable, even if the organization did not agree with some of the proposed ideas.

Some of the actions taken by the organizations we examined could be applicable to NIGMS. To improve preparation for Council, the Institute could invite new members to the meeting preceding their official appointment (Institute 1). As many NIGMS Council members reported being surprised at what took place at the sessions, exposing them to the meetings in advance may ease the adjustment. Similarly to Institute 1, NIGMS could interview new and retiring members to gauge their level of satisfaction with Council proceedings. The Institute could reach out to Council to identify the areas the members are interested in exploring as a group (Institute 4). This is a simple step, and according to Institute 4, a very effective one. Finally, the Institute could carve out some time for the discussions of the NIGMS current portfolio and possible future directions, and ask the members to bring their ideas to the table (NSF and HHMI).

Chapter 5: Recommendations

In this chapter, we suggest three possible courses of action for NIGMS, along with specific recommendations under each. The options presented are not mutually exclusive and the recommendations under each option could be combined in multiple ways to best meet the needs of the Institute.

Option 1: Continue with current Council emphasis and procedures.

NIGMS Council is well run and most members and NIGMS staff is satisfied with its functioning, therefore, maintaining the status quo is a viable option. However, we have a few specific recommendations for improvements within the current structure.

Recommendation 1.1: Reach consensus among the staff about the desired use of Council.

There was some variation among NIGMS staff on what they perceived the role of Council to be, and what they thought it should be. Some NIGMS staff advocated greater engagement of Council in policy matters, others in setting policy and science directions, yet others were satisfied with the current level of contribution. We suggest that the Institute formalize its policy about what types of issues should be brought to Council, at what stage in the decision-making process Council advice should be sought, and in what format their input can best be solicited.

Recommendation 1.2: Clarify and communicate when and how staff can interact with Council.

Some NIGMS staff members were uncertain about the acceptable level, types and venues of communication with Council members. We suggest clarifying to all professional staff what discussions are appropriate and whether these should take place directly with Council members, through the Executive Secretary, or through some other party. New employees could be given guidance regarding Council during their orientation.

Recommendation 1.3: Implement a mechanism for reporting to Council what actions NIGMS took as a result of Council input.

Both NIGMS staff and Council members were generally satisfied with the level of involvement of Council in policy and direction setting. However, at time Council members were uncertain about the steps that were taken once they had provided recommendations. A more formal mechanism to communicate how NIGMS responds to recommendations, even if the Institute had decided against the proposed idea, would ensure that Council remains informed.

Options 2: Increase Council efficiency without expanding its role.

Council members reported to be unprepared for the amount of work that was expected from them before each session and in some cases made arbitrary choices on what materials to review to manage the workload. In addition, some respondents viewed staff presentations during the sessions as too lengthy and unnecessarily detailed. Minor changes in how new members are prepared for their roles and in the format of Council sessions could increase the efficiency of Council.

Recommendation 2.1: Better prepare Council members for the scope of their responsibilities and suggest strategies for prioritizing assignments

While most Council members were happy to contribute their time and effort, they would have appreciated more guidance from the Institute about how to make the workload more manageable. We suggest that NIGMS staff inform new and ad hoc members during pre-Council briefings on the range and scope of the assignments they will receive, when to expect these assignments, what aspects of the assignments to focus on, given limited time, and what type of information individual members should provide about their assignments during Council.

Recommendation 2.2: Link new and established Council members and provide opportunities for incoming members to witness Council proceedings prior to their first session.

New Council members who took the initiative to contact experienced members in preparation for Council viewed their discussions as valuable. NIGMS might consider establishing a more systematic buddy system that links new and practiced members. Alternatively (or in addition), NIGMS might invite Council members to the meeting preceding their official tenure, so that they can witness Council proceedings firsthand and have the opportunity to ask questions.

Recommendation 2.3: Limit staff presentations during Council to use time more efficiently.

Some presentations by NIGMS staff were seen by respondents as too detailed and too long relative to the importance of the topics to the Institute. Setting and enforcing shorter time limits would free up valuable Council time, which could be used to greater advantage by NIGMS.

Option 3: Enhance Council participation in the setting of policies and scientific direction.

As Council typically responds to the items brought up at the sessions, NIGMS does not take full advantage of the talent and experience of the group in setting policy and scientific direction. If the Institute wishes to engage Council more fully, we recommend taking several steps.

Recommendation 3.1: Redefine Council's role in advising the Institute about policy and science.

Council members did not think that NIGMS was interested in their input outside of peer review and the approvals of new initiatives. Therefore they do not engage in more efforts to influence policy and direction. If the Institute decides that Council should be more involved in setting policies and research directions, this role should be explicitly conveyed to Council members and to NIGMS staff. To address this issue, it may be necessary to set aside time to engage the Council on current/future directions.

Recommendation 3.2: Expand opportunities for Council to influence Institute policy.

Because of the full schedule during Council, there are few opportunities for Council members to have substantive discussions not directly related to Council matters. If NIGMS is interested in engaging Council to a greater extent, the first step might be to determine what topics are of interest to the members and in what areas they see themselves as most able to contribute. This information can then form the basis for charging Council members with specific projects.

In addition, NIGMS would need to create a venue for Council to offer advice. Periodic retreats or entire open sessions dedicated to this purpose are possibilities. If this level of resource investment is unrealistic for the Institute, we believe that small changes to the current format can make a difference to the level of Council participation. For example, NIGMS can carve out some time for the members to discuss ideas, which can then be presented to the Institute. NIGMS can set up periodic one-on-one meetings between Council members and the Director, so that the members can broach ideas in a more intimate setting. Finally, since the break-out sessions were identified as a more conducive setting for offering advice than full sessions, NIGMS might consider establishing sub-groups for the three divisions that currently meet only in full sessions (Minority Opportunities in Research Division, the Center for Bioinformatics and Computational Biology, and the Training Program Projects and Centers).

Recommendation 3.3: Seek Council input at an early stage of program development.

NIGMS staff members typically present concepts to Council at a late stage in the program development process, after extensive internal consideration. We suggest engaging Council in the discussion early, when the ideas are not fully formed, to avoid creating an impression that NIGMS has already committed to the concept and the advice is sought pro forma. If soliciting Council views at an early stage is not practical, the members should be encouraged to exercise the opportunity to postpone voting until a subsequent session.

Appendix: Other Advisory Councils

Institute 1

Identification and preparation of members

Throughout the year division directors and members of professional societies submit nominations for Council to the Executive Secretary. The Executive Secretary limits the list to the candidates appropriate for replacing the retiring members and the short list is reviewed by the Director. According to the Institute staff, ideal scientific Advisory Council members are individuals who are not only well established in their fields, but who can see beyond their individual professional interests. Lay members are recruited from advocacy organizations and editorial boards of professional journals.

New members are provided with access to the Electronic Council Book, which contains various orientation materials. The Institute generously shared with us one of these internal documents, a 5-page introduction to Council. The document begins with a description of Council roles and we noticed that advising the Institute on program planning and policy was listed first, followed by the review of applications (we do not know whether this order was meant for emphasis). The open session is presented as being exclusively devoted to policy and planning; the type of guidance that Council provides to the Institute is briefly mentioned. The next portion of the document delineates Council roles in the review of applications, which take place during the closed session. The document offers specific instructions on Council actions related to appeals, foreign applications, merit extensions, and review-related activities.

In addition to the written materials, the Institute holds telephone briefings with all new members. Finally, all freshmen are invited to attend a Council meeting preceding their official appointment (for example, members joining Council in May would attend the January session). New members can participate in all activities of this preliminary Council, but have no voting rights until their tenure formally begins. When asked about the level of preparedness of Council members, we were told they "do their homework" on applications, but are most effective in the policy arena.

Engagement in policies and research directions

According to Institute 1 staff and the materials distributed to new members, the Council performs two functions: review of grant applications (in closed session) and discussion of policies and ideas on how to better service the Institute's scientific community (in open session).

Council has an opportunity to offer advice on research and policy in the course of various regular and ad hoc activities. First, Council members review program plans and participate in concept clearance. Once proposals in response to an RFA are received, Institute 1 staff review the portfolio with Council; during the review, the Institute's funding priorities are also discussed. Second, the Institute convenes the Board of External Experts twice a year, which includes some representatives from the Advisory Council. All Council members can attend these meetings as guests and contribute

to the discussion. The role of the Board is to assess and prioritize ideas for new RFAs and PAs. Information emerging from the Board is presented to full Council at the next session and any suggestions made are brought back to the Board. Third, in 2009 Institute 1 joined a consortium of health agencies committed to fight against several common diseases. Institute staff engaged Council in the discussion of the role the Institute should play in this alliance. Finally, on occasion Council members ask the Institute whether and how research in specific area is being supported. In response, Institute 1 conducts portfolio analysis and reports back to the Council.

When asked to give a specific example of Council contributing to a policy or a research priority, the respondent said that following a Council suggestion the number of training grants Institute 1 received and reviewed was reduced. He noted that the Institute generally follows Council's recommendations, although its activities are somewhat orchestrated by the Institute. Institute 1's Council is in session for one day and there is little communication with the members between sessions.

Other relevant information

The Institute has started implementing telephone surveys of Council members, after the first meeting and at the end of tenure. In the interviews, the members are asked how to improve Council functions.[18]

Institute 2

Identification and preparation of members

Nominations for Council are made primarily by the Institute staff, both scientific and administrative (scientific officers propose individuals who will fill their programmatic niche). On occasion, professional societies and Council members also submit nominations. Once the list of candidates is compiled, it is discussed with all program staff. Lay Council members are often former scientists who transitioned to non-research academic positions, such as university administrator.

New members receive an orientation handbook that contains information about the composition of the Council; charge to Council; and background on the Institute, including the types of research and training being supported. The handbook also contains a description of a typical Council meeting, including what occurs at open and closed sessions. Documents provided to the members have been developed by the Institute and are revised every year.

In addition to these materials, on-boarding of new Council members includes an orientation session, which takes place the afternoon prior to the first meeting. During the orientation, staff discusses the mutual responsibilities of the members and the Institute, the program review process, and other topics.

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[18] The respondent was reluctant to share interview data as they were still limited at the time of the interview.

Before each Council meeting, all members receive a large volume of materials. To ease the transition for new members, the Institute provides them with short explanations of Council procedures. For example, new members are told that for high program priorities the Institute staff will make the initial recommendation, and after that the Council members will have a chance to express their opinions.

Finally, the Institute has a password-protected website to retrieve confidential materials. The website also contains information on Council practices, for example an explanation of high program priorities and a reminder not to discuss Council matters outside the sessions.

Engagement in policies and research directions

We were told that Institute 2's Council roles focus primarily on the review of initiatives and grant applications. As at other Institutes, the Council has an open and a closed session, each serving a different purpose. Proposals are reviewed during the closed session, and sometimes discussions of research directions and priorities take place at this time. Council has another opportunity to give advice to the Institute during the open session. During this session, the Institute staff and the Director speak to Council on budgetary matters, as well as on policy changes at the Institute and at the agency level. The members are free to ask questions and make comments during these presentations. The respondent noted that the number of items discussed during the open session is fewer than in the past as Council is no longer involved in concept clearance (for the past eight years or so, the Institute has engaged expert panels for this purpose).

At Institute 2, Council is involved in the review of intramural research activities. The members are provided with an annual report from the director of intramural research; every five or six years Council is charged with evaluating the scientific direction of the Institute's intramural program. Another venue for Council to steer the Institute is the Strategic Plan review, which occurs every three years. The Council takes a lead on this activity, usually through a subcommittee enhanced by outside expertise. Finally, while this is not a formal charge, some Council members participate in technical workshops to explore the Institute's scientific direction.

Proceedings from Council are captured in the minutes or in a brief email communication. The minutes might include recommendations made at the meeting and follow-up items requested by Council. For the follow-up requests, the Institute staff members taking the lead are identified.

The respondent could not think of a recent example of a research direction or policy suggested by Council, which has been adopted by the Institute. However, he said that there are specific areas where the Institute seeks Council involvement. These include advice on high program priority areas and on how to respond to letters from new investigators.

Institute 3

Identification and preparation of members

According to the interviewee, the broad and diverse mission of the Institute necessitates three separate Councils. Division directors work with staff to identify members, who are then vetted by the Institute Director. After being approved by the leadership of NIH, the nominations are submitted to DHHS. The respondent told us that on occasion DHHS has eliminated or added candidates.

The composition of Council has to satisfy two broad mandates. "From the management perspective," it must be diverse in gender, ethnic/racial composition, and institutional affiliation of the members. "From the Institute's mission perspective," the members should be broad thinkers, who can view their field from a higher level and who represent the areas relevant to Institute 3. The membership is biased toward MDs engaged in basic research (the respondent noted that clinical MDs would be welcome, but are very difficult to recruit).

In advance of the first meeting, new members are provided with a bound volume that contains extensive information about NIH, including policies and procedures related to peer review. The respondent noted that lay members may not be familiar with the details of the grant process, and could benefit from this type of background information. We reviewed this volume, called the Advisory Council Orientation Handbook, which can be obtained on the Institute's website. Two of the chapters in the Handbook, which is almost 300 pages long, are devoted to the Advisory Council's operating procedures. The chapters cover composition, roles, and activities; laws and regulations governing Council; sample agendas and meeting minutes; and recent reports from the Director accompanied by questions raised by Council and the responses given by the Institute. In addition to the Handbook, new members meet with the Institute's senior staff the day before their first meeting. The Institute Director gives a 45-minute presentation, introducing the Institute and the Council operating procedures.

Engagement in policies and research directions

Council at Institute 3 performs two functions: review of grant applications (in closed session) and discussion of policies and ideas on how to better serve the Institute's scientific community (in open session). When asked to give an example of a major policy or research-related decision made by the Institute with Council's input, we were told that the Institute terminated its participation in the R21 program. This decision was based on considerable research by the Institute and on deliberations of Council.

Council is engaged in advising the Institute via several mechanisms. First, Council members are sometimes invited to serve on expert panels that develop research plans for each division; once agreed upon, the plans are reported to full Council. Second, grant reviews and concept clearance offer an opportunity for Council input. Finally, the Institute organizes short scientific presentations, which sometimes prompt discussions related to the Institute's scientific direction. The level of participation of Council members in the discussion of research and policy varies. Some members—

political appointees and lay public in particular—are less involved and more difficult to use in the advisory capacity.

The Institute Director and the Executive Secretary report back to the Council on the actions taken by the Institute. On occasion, information related to Council business is provided to the members between sessions. The interviewee noted that lack of familiarity with the Institute's portfolio could pose problems for an effective use of Council. For example, program staff may have decided against funding a meritorious proposal in an area that is already well supported by the Institute. As Council members do not have that knowledge, they might oppose this decision.

Other relevant information

The interviewee seemed to be familiar with the activities of NIGMS Council. In his opinion, NIGMS Council feels "more empowered" than Institute 3 Council. At Institute 3, the Council members understand that with rare exceptions (made for new PIs or orphan diseases), proposals beyond the payline would not be funded. Further, in contrast to NIGMS which considers a large number of appeals, Institute 3 receives one appeal per Council meeting, on average. Because of these differences, Institute 3's Council has less freedom to affect the granting process. This respondent recommended that NIGMS staff attend Council meetings at other Institutes, as the social dynamic can vary dramatically across Institutes.

Institute 4

Identification and preparation of members

Each year, Institute 4 solicits Council nominations internally and from the public. Reviewers, staff, advocacy groups, and alumni Council members submit suggestions for new members. The Institute seeks individuals who have the wisdom to "look beyond parochial interests" and the broad knowledge of research areas related to the Institute's mission.

In the past, new members visited the Institute for a day to observe the Institute's processes; at present, this introduction is done by videocast. Additional instructions are provided via multiple telephone calls, in which important policies, such as confidentiality and conflict of interest, are reiterated. Council members are provided with hard copies of various materials, which are discussed during the videocast and phone calls. "As a booster," Institute 4 holds an in-person orientation meeting for the freshman members before their first session. Respondent noted that while new Council members seem to be reasonably well prepared, the first meeting still tends to "come as a shock." If the Institute plans to bring an important issue before Council, the members are alerted about it in advance and provided with relevant background documentation.

Engagement in policies and research directions

Like other Institutes, Council at this Institute has two main functions: secondary review of applications and general advice to help the Institute understand the researchers' perspective. As

the respondent put it "the community lets us know what they think and we let them know what our stakeholders need."

During the open session of Council, the Institute discusses their "big ticket items." Occasionally, the members ask to form a working group to investigate progress in some research area, to help them provide more informed advice. Requests for these in-depth studies are typically prompted by an application being reviewed or by a scientific article that someone has come across. The Institute staff said that the information resulting from these working groups has been very helpful to the Institute.

Asked to provide an example of Council's input into the Institute's activities, the respondent told us that they have been steered toward more extensive resource/data sharing policies and procedures. Council members have strong convictions that data generated with the Institute's funding should be made available to the entire community.

Communication between the Council and the Institute takes place during the meeting, at dinner after the meeting, or via email. To avoid any conflict of interest or its appearance, any communication between the Council and the Institute staff goes through the Executive Secretary.

The respondent noted that the advice that the Council can provide "is only as good as the information they have." Like representatives from other Institutes, Institute 4 staff raised an issue of familiarizing a transient group of Council members with the multitude of activities funded by the Institute. We were also told that Council members requesting various background data from the Institute do not appreciate the volume of the information they would need to absorb to get up to date. Institute 4 staff members try to educate Council by providing aggregate data on budgets, PIs, division and branch structures, and strategic objectives, but the respondent noted that regardless of what data items the Institute provides, the Council is always seeking additional information.

Other relevant information

The respondent shared with us that Institute 4's Council used to be relatively unengaged. To engage Council more fully, the Institute staff asked the members to anonymously convey to them the items they wanted to discuss during the open and the closed sessions. This strategy proved to be very effective: as the interviewee put it, "pretty soon you could not stop them" and "now they are a rowdy bunch." The energy of the meetings has since been maintained, as new members observe the lively dynamic of the Council and feel comfortable expressing their views.

Institute 5

Identification and preparation of members

When a Council member is retiring, the Executive Secretary notifies the Institute staff that an opening is coming up in a particular area. Members in the public domain are generally drawn from the advocacy groups for the numerous diseases within the scope of the Institute; attempts are made to balance common and rare diseases. Suggestions from staff and from the departing members are

discussed at the staff meeting and finalized by the Institute Director. Under the previous administration, DHHS added and removed the names from the list, but as of late all of the Institute's nominations have been approved (albeit sometimes after a long delay). Ideal members should be able to "take their individual hats off" to see the science from a broader perspective. In addition, Council expertise has to span the areas supported by Institute 5. Finally, the Institute seeks wide gender, racial, geographical, and institutional representation.

All freshman members attend a 2-hour orientation the night before their first session. The Executive Secretary makes a presentation, explaining Council rules as well as what to expect at the session. Hard copies of various materials are provided to new members before the orientation. The Executive Secretary remains in close contact with the members. If an important issue is planned for Council, all members are alerted in advance. In the opinion of the interviewee, Council members appear prepared for their roles and responsibilities.

Engagement in policies and research directions

Similarly to other Institutes, Council at Institute 5 has closed and open sessions. In closed sessions, Council considers the proposals scored close to the payline. The Council also provides input on the set of applications received in response to RFAs and PAs. These discussions typically take 2–3 hours. During open sessions, Council considers new programs for concept clearance and reviews new Institute policies.

The philosophy of the Institute as communicated by the respondent is that Council members have been selected for their talents and standing and, therefore, should be engaged in making important decisions ("Council members are not presented with FYIs"). The interviewee offered several examples of how Council has contributed to the Institute. Institute 5 is considering terminating support for R21 grants and Council members have been actively involved in this discussion; the Institute will most likely either follow their advice or at least consider it very seriously. In a minor example, Council persuaded Institute 5 to change its funding plans for a stem cell center; in retrospect, it was the right decision. Finally, Council requested that the Institute conduct a portfolio analysis in order to identify features of successful research projects ("success" could be defined as FDA approval, for example). The Institute selected 10 major advances made by their grantees and tried to determine what made them succeed. An 80-page narrative resulted from this effort.[19] The respondent acknowledged that while this exercise did not bring about significant policy change, it had a subtle effect on how the Institute apportions funding for the investigator-initiated versus Institute-initiated research programs.

The respondent identified several venues to engage Council. In addition to the discussions that take place during regular sessions, every few years Council is heavily involved in a strategic planning process. Recommendations from expert planning groups convened to assist the Institute in the process are reported back to full Council. Council members participate in various scientific

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[19]   Institute 5 staff found that in most cases the researchers who made the discoveries were not supported by R01 grants, but rather by programs initiated by the Institute's staff (RFAs and PAs). The staff concluded that it was worthwhile to set aside funds for initiatives.

workshops, which examine possible research directions for the Institute. Finally, Institute staff members periodically ask Council to recommend items for discussion; we were told that Institute 5 welcomes controversy and that any topic is open for discussion.

During the interview, we asked whether conflicts ever arise within Council or between the members and the Institute staff. We were told that while this occasionally happens, consensus is typically reached, or at least there is a "sampling of opinions" to guide the Institute's decisions. The respondent noted that some Council members are opposed to all programs initiated by program directors. Since program directors at the Institute organize in units by scientific interest, it is easier for them as a group to defend their initiatives.

Institute 5 does not have a formal system for reporting to Council on the actions taken by the Institute. In some cases, the members ask for a follow-up and it is provided. For example, the Council was updated on the discussion of the fate of R21 program. The Institute conducted an evaluation of the disease center and the report was presented to Council. The respondent admitted that reporting was somewhat insufficient, but noted that this was due to inconsistent internal program monitoring and evaluation rather than to any communication failures with Council.

Other relevant information

The respondent reiterated forcefully that the Institute uses Council only for important decisions and that staff are trying to be strategic about the items that are brought to Council during the open sessions.