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**POST-AWARD MANAGEMENT OF THE NATIONAL  
INSTITUTES OF HEALTH NANOMEDICINE INITIATIVE  
NANOMEDICINE DEVELOPMENT CENTERS**

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## **Project background**

This project is an amendment to task order OSTP-20-0002.23, for work to be performed by the Science and Technology Policy Institute (STPI) of the Institute for Defense Analyses (IDA) under Contract Number OIA-0408601 in support of the Office of the Director of the National Institutes of Health (NIH). The financial sponsor for this task is the National Science Foundation (NSF). STPI is a federally-funded research and development center that provides technical and analytic support to the Office of Science and Technology Policy and the Federal R&D community. The financial sponsor for this task is the National Science Foundation (NSF).

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## Abbreviations

ECG	Extramural Consultant Group
FFRDC	Federally Funded Research and Development Center
FRA	Flexible Research Authority
IDA	Institute for Defense Analyses
NDC	Nanomedicine Development Center
NEI	National Eye Institute
NIH	National Institutes of Health
NIPT	Nanomedicine Implementation Project Team
NSF	National Science Foundation
OSTP	Office of Science and Technology Policy
STPI	Science and Technology Policy Institute

## **1. Executive summary**

### **1.1. Introduction**

In spring 2008, the Science and Technology Policy Institute (STPI) at the Institute for Defense Analyses (IDA) began a study of the management of the National Institutes of Health (NIH) Nanomedicine Development Centers program. The management study was funded as an extension of a previous evaluation of the processes with which the program solicited and selected the eight current Nanomedicine Development Centers (NDCs).

During the course of this study, STPI conducted a series of interviews with NDC program participants, including Nanomedicine Implementation Project Team (NIPT) personnel, Extramural Consultant Group (ECG) members, and the principal investigators from each of the NDCs. Program documents were used as additional sources of information.

This study was envisioned as both a descriptive and evaluative effort. One goal was descriptive insofar that NDC program leadership has had some flexibility (relative to other programs at the NIH) in their management of the program's centers. Accordingly, this study describes the portfolio of "mechanisms" used by the NIPT (often with the help of the ECG) for program management:

- Annual meetings
- Site visits
- Progress reports
- Set-aside funds allocations

Another goal for the study was evaluative in that the perceptions and attitudes of program participants can help to identify the strengths and weakness of each mechanism. This "multiple perspectives" approach is common to management studies (e.g., across the fields of strategic management, industrial organization, and transaction cost economics) and can inform current practices. Importantly, this approach is not designed to evaluate specific outcomes (e.g., center productivity), but rather more broadly the "effectiveness" and "efficiency" (defined below), among other factors, of management and operations at the program level.

### **1.2. Method and approach**

This study is qualitative, based on semi-structured interviews with NIPT chairs and personnel, ECG participants, and NDC directors. The interviews focused on the four mechanisms identified above used to manage the NDC program. Specifically, respondents were asked about the "effectiveness" and "efficiency." Mechanism effectiveness was not defined for the respondents. Rather, they were asked to identify the goals of the mechanism, as they saw them, and then they were asked to report on the extent to which they perceived these goals to have been attained. Efficiency also was not defined for the respondents, but rather study participants were asked to identify specific activities for each of the management mechanisms that they felt facilitated or hindered the attainment of their goals.

It should be reiterated that the unit of analysis for this study is the *management of the NDC program as exercised by the NIPT*, with the assistance of the ECG, and not management of each of the individual NDCs. Therefore, characterizations in this study of particular management mechanisms as “effective” and/or “efficient” does not constitute an evaluation of the specific centers. This type of summative analysis is reserved for future outcome evaluations employing quantitative operationalizations of effectiveness and efficiency emphasizing the scientific productivity and progress toward clinical application of the centers.

During the interviews, respondents were also asked to identify what they perceive to be the most valuable aspect of the mechanism in question. For instance, many ECG participants suggested that the most valuable aspect of the annual meetings has been the poster sessions. Moreover, many NIPT personnel characterized as the most important aspect of site visits the opportunity to observe center leadership, faculty, and post-doctoral researchers and graduate students interact during question-and-answer sessions that follow the presentations.

The interviews concluded with questions about suggested changes for each mechanism and then more general questions about the NIPT. This component of the interviews was necessarily less structured (i.e., the questions were relatively open-ended) and took on the tone of an informal conversation.

In total, this study includes interview responses from 1 of 2 NIPT chairs, 12 of 15 NIPT personnel, 6 of 8 ECG participants, and 7 of 8 NDC directors. For full information regarding the method used for this study, see the appendices to this report.

Finally, it is important to note that in a qualitative case study, statistical inferences need not and cannot be made. For example, the perspective of one ECG member could be of greater insight and value to the program than a common (and perhaps contrary) perspective shared across all other external consultants. Accordingly, the findings in this report are presented as-is. When interpreted in this Executive Summary, weight is given to the study team’s perceived value of the perspective and not to the quantity of interviewees supporting that perspective. However, some highly “valued” perspectives may be shared across numerous or even all interviewees. Moreover, the quantity of quotations to support one perspective versus another is a function of the data, not of the perceived importance of a particular perspective on the part of the study team.

### **1.3. Findings in brief**

This study was organized around assessment of the effectiveness and efficiency (as defined above) of three of the four mechanisms used by the NIPT to manage the eight NDCs: annual meetings, site visits, and progress reports (hereafter collectively referred to as the “management mechanisms”). This study inquired as well about perceptions of the NIPT, ECG, and NDC directors of the set-aside funds allocations. These “base findings” are summarized here, though this report includes an empirical chapter devoted to each mechanism and topic (see sections 2 through 6 below). Accordingly, the presentation here is summary and brief.

In addition, a number of themes emerged from the interviews that speak across the management mechanisms that were the original foci of this study. These “collective findings” address the complementarity of the mechanisms as a management portfolio, the contingent basis upon which some of the mechanisms have been used, and the many informal management tasks performed by the NIPT that, from the perspective of many program participants, are as important as the formal management mechanisms.

## **Base findings**

### Effectiveness and efficiency

With few exceptions the participants in this study considered the goals for the awardee meetings, site visits, and progress reports to have been effectively attained. Moreover, the goals identified across the participant groups for each of the management mechanisms suggest that there is goal consensus across the NDC program. In none of the interviews was there evidence of divergent perspectives of the purposes or intentions of the interactions (between the NIPT, ECG, and NDC leadership and faculty) that occurred during the annual meetings, site visits, and progress report processes. This finding is notable given that the NDC program is still somewhat new.

The interview findings suggest that each of the management mechanisms is perceived across the participant groups as efficient. There were very few suggestions for revising or omitting existing activities; and few suggested adding new activities to the annual awardee meetings, site visits, and progress report processes. One exception was responses from a small number of ECG participants and NIPT personnel that sometimes the site visits can be “too formal” and therefore less conducive to the types of informal and focused discussions and interactions between the site visit team and center leadership that the visits are intended to facilitate.

### Appropriateness of set-aside funds allocations

All of the respondents to this study characterized the use of set-aside funds thus far as appropriate. However, some did have recommendations for future use. A notable recommendation was to use some of the funds for “informatics infrastructure” whereby a common database tracking project data and results across the NDCs would be constructed for common access and use across the NDC program. Another recommendation was to use set-aside funds to broaden participation in the center’s activities by funding outside investigators. A last recommendation of note suggested a needs-based approach for determining set-aside funds amounts and recipients.

### Perceptions of the NIPT and the ECG

This study was also designed to discern any “expertise gaps” on the NIPT and ECG rosters. NIPT personnel, ECG participants, and NDC directors were asked about their perceptions of the “span” of scientific and technical expertise represented by the NIPT and by the ECG. Interviewees were not asked about their same-group colleagues. For instance, ECG participants were asked about their perceptions of the NIPT, while NIPT personnel were asked about the ECG. NDC directors were also asked about their perceptions of the teams of ECG participants

and NIPT personnel with whom they interact at the annual meetings, during site visits, and during the progress report review and feedback process. Generally, all respondents indicated that the NIPT and ECG are appropriately staffed in terms of scientific and technical expertise.

## **Collective findings**

### Complementarity of the management mechanisms

It became clear during this study that, collectively, the site visits, annual awardee meetings, progress reports, and set-aside funds allocations constitute a portfolio of management mechanisms that enables the NIPT to address both the research and management aspects of the NDC program. Generally, the mechanisms were characterized as providing different types of information that together aid in the evaluation of each NDC and the program as a whole.

The chapters below presenting the “base findings” on each management mechanism confirm this complementarity. It was often difficult for study participants to discuss the goals and value of one of the mechanisms without explaining how these complement the other mechanisms. A meta-analysis of the base findings suggests that the annual meetings provide information regarding a center’s broad-based goals and “fit” within the program vis-à-vis the other centers, the site visits provide information about the management and collaborative culture of each center in addition to more in-depth discussion of research, while the progress reports codify all of the center’s accomplishments, specifically those related to dissemination efforts such as publications and presentations.

### Contingency management style

One of the challenges that the NDC program faces is limited resources, especially the time of NIPT personnel and ECG participants (see further discussion below). One common management response to resource scarcity is to manage on a contingency basis, using resources strategically (Rainey 2003). This study reveals evidence that the NIPT is doing this with regard to the time commitments of its personnel and the time commitments of ECG participants. For example, though the site visits were initially a mechanism used for all centers, more recently they seem to have been reserved primarily for NDCs perceived to be “problematic” either in terms of the direction of their research or center management, based on information from the annual meetings and progress reports.<sup>1</sup>

### Informal and accessible management style

Study participants also emphasized the accessibility of the NIPT, especially of the NDC program director, Richard Fisher. Dr. Fisher has been readily available to NIPT members, ECG participants, and NDC leadership throughout the program.

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<sup>1</sup> It should be noted that there is not always consensus amongst the NIPT and ECG that a particular NDC is “problematic.”



## **1.4. Challenges and recommendations**

Based on the findings summarized above, the management of the NDC program has been effective, efficient, and has used funds appropriately. These successes seem to have been a function of the management style of the NIPT, which has used complementary mechanisms to gather information about the NDCs' progress and barriers, in some cases on a contingency basis, in addition to engaging in informal interactions with center leadership when required. However, with each of these successes come challenges. The most formidable of these challenges relates to the time constraints of NIPT and ECG personnel. This and other challenges are discussed below. Some challenges are accompanied by recommendations while others require further study.

### **Divergent perspectives of the centers**

As the NDC program matures, the need for an outcomes-based evaluation of each of the centers is fast approaching. One observation from the interviews that was not directly related to the management focus of this study was that there exist divergent perceptions and expectations of the NDCs among the NIPT and ECG. Specifically, while some of the interviewees expressed satisfaction with the progress and direction that each of the centers have taken thus far, others were more critical, maintaining that as many as half of the centers seem to be lacking either in terms of the quality of the science being conducted therein or in terms of progressing towards programmatic goals.

While it was not a goal of this study to consider center performance, these divergent perspectives of current center performance are suggestive of future program management and implementation barriers, especially regarding the eventual summative evaluation of each of the NDCs. Accordingly, the NIPT should start the center evaluation planning process sooner rather than later.

Specifically, because of the newness of the field and because of the breadth of scientific and technical foci across the centers, we recommend the development of a strategic plan for the eventual evaluation processes. The plan should have input from all relevant participants and be used to generate consensus across participants as to the expected outcomes and performance criteria for each of the NDCs. Based on the divergence of perspectives expressed in this study, at this point in time (pending further inquiry) we suggest that the program take a contingency approach, considering expected outcomes and criteria that speak to programmatic goals<sup>2</sup> on a center-by-center basis.

### **Lack of expertise in organizational design and behavior**

The NIPT personnel and ECG members who participated in this study consistently emphasized the importance of observing the interactions among each center's leadership, faculty, and other

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<sup>2</sup> The RFA goals appear to be such that a contingency approach is feasible. The RFA from the second group of NDCs (RFA-RM-06-005), for example, lays out one overarching goal and three sub-goals for the centers. Though each NDC likely will approach these programmatic goals in a different fashion (since the capabilities, engineering principles, and interventions may vary), the program and individual centers can still be assessed relative to whether progress toward them has been achieved.

personnel (e.g., post-doctoral researchers), especially during site visits. Observing interactions was intended to identify the extent to which the center is “behaving like a center” – i.e., engaging and collaborating as a research unit with a unified purpose rather than as a loosely-conjoined group of individual investigators. Yet, the NIPT and ECG personnel interviewed have applied only loose heuristics for making this type of observation. For instance, one respondent reported that “one knows a functional center when one sees it.”

The centers visited perhaps have incentive to steer attention away from any dysfunction that may exist. Therefore, the NIPT and ECG should become more systematic and unified in addressing the organizational and management aspects of each of the NDCs. There exists a growing field of practice using propositions from the management sciences and from theories of organizational behavior and leadership to assess organizations like university research centers. Though the interviewees for this study were unanimous in agreeing that the NIPT and ECG rosters contain no gaps in scientific and technical expertise, one recommendation along this line is that the ECG be expanded to include a management specialist to aid in the evaluation of those centers perceived as having management or leadership problems.

### **Communication of expectations for the site visits**

The ability of the NIPT to make appropriate decisions regarding each of the NDCs is a direct function of the information gathered about each NDC, per the management mechanisms considered in this study. The information gathered at site visits was not perceived as satisfactory by some of the NIPT and ECG personnel who participated in this study. Some considered the site visits as too formal and therefore as less conducive to observing centers’ workaday management and operations, which was a primary site visit goal for many interviewees (see above). Specifically, information gathered on some of the site visits was viewed as having too much overlap with that gathered at the annual awardee meetings.

This complaint seems to have been in part related to the fact that some site visits coincided with centers’ internal annual meetings. However, for geographically dispersed NDCs, these internal meetings provide a rare opportunity to observe center participants interact. Given that site visits in the future will likely be reserved for centers viewed as “problematic” in one regard or another (see above), it is imperative that the organization and structure of the visits are such that the site visit teams can easily gather the information required to make sound decisions and to provide sound advice. Moving forward, the NIPT should ensure that centers to be visited are informed of the site visit team’s expectations prior to the visit. Specifically, the site visit team should communicate whether they want to spend the visit in a structured manner – e.g., listening to presentations and touring facilities – or whether the site visit should be less formal – e.g., without a strict agenda, formal presentations, and the like.

### **Time constraints**

Practically all of the NIPT and ECG participants in this study mentioned at some point during the interviews that they do not have enough time to fulfill (to their satisfaction) their responsibilities to the NDC program. One NIPT member succinctly observed that “all of [program management and leadership] have day jobs.” Of course, this is common for professional scientists and

engineers and there is no ready solution. Insofar that Flexible Research Authority requires more active management than passive administration, there are a number of considerations to make. First, ECG members perhaps should be recruited based on their ability to participate. For instance, a couple of the external consultants interviewed reported that they have not yet participated in site visits due to time constraints. The other consideration is of course to allocate more NIPT personnel time to the program, though the benefits and costs of this should be considered more formally than in this report.

### **1.5. Further study**

The findings of this assessment of the post-award management of the NDC program demonstrate that program participants perceive the NIPT to be managing the program both effectively and efficiently. Therefore, although recommendations are made for improved program management, further inquiry into program management is unnecessary at this time. The next assessment should be an outcomes-based evaluation of center performance, though we recommend (see above) that the NIPT and ECG engage in an evaluation planning process to ensure that this evaluation focuses on the appropriate outcomes and will directly inform future decision making.

## 2. Annual awardee meetings

The first component of the interviews conducted for this study addressed the annual meeting in which the Nanomedicine Implementation Project Team (NIPT), Extramural Consultant Group (ECG), and Nanomedicine Development Center (NDC) leadership and faculty participate. This section summarizes the findings for this component of the study and is empirical.<sup>3</sup> No quantitative decision rules were used for inclusion or exclusion of the findings. Both unique and common perspectives are presented.

### 2.1. Brief description

The NIPT has organized two annual meetings since the inception of the NDC program. The first annual meeting took place in Bethesda, Maryland on March 1-2, 2007. The second annual meeting took place at the University of California at San Francisco on April 2-4, 2008. The 2009 annual meeting is being planned for Bethesda.

The annual meetings are designed bring together key NDC program participants: the NIPT, members of the ECG, and approximately 15-20 participants per NDC, including faculty, post-doctoral fellows, and graduate students. The annual meetings begin with “overview” presentations by the center directors. These presentations are broad in scope relative to subsequent meeting presentations. After these introductory presentations, scientific presentations follow, which allow time for questions and discussion. Each of the annual meetings also included a poster session. The presentations and poster sessions are open to all meeting participants.

The second day of the annual meetings includes closed-door meetings. First, the NIPT and ECG meet to discuss the progress of the centers and plans for future funding and program direction. Second, the NIPT and ECG meet with the NDC directors as a group. The NIPT uses this latter meeting as an opportunity to receive feedback from the centers and to communicate future opportunities to compete for set-aside funding.

In addition to presentations and formal interactions, the annual meetings include numerous opportunities for informal interactions. The poster sessions, joint meals, breaks between presentations, and evening receptions provide time and opportunity for face-to-face discussion amongst participants.

The purpose of the annual meeting evolved between the first and second iterations. The first meeting was predominantly informational (versus evaluative). The chief intent was for the center leadership to meet and for the NIPT, ECG, and center directors to learn about each of the centers as they started up.

The second annual meeting was somewhat more evaluative in tone. The NIPT and ECG used this meeting to communicate feedback both informally as well as in closed-door sessions.

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<sup>3</sup> For a full description of methodology, see Appendix A.

## **2.2. Goals and goal attainment**

One of the purposes of this study is to identify variable perceptions of the goals of the annual meeting, insofar that a lack of clarity in or agreement over goals can lead to “ineffective” use of resources in public programs and organizations (Rainey 2003). The study found evidence that the goals of the annual meeting are clearly understood across the key participant and stakeholder groups (i.e., NIPT and ECG personnel, NDC directors). The study also found evidence of consensus that the annual meetings have fulfilled these goals.

The participants interviewed for this study identified a number of goals the annual awardee meeting is intended to attain, which may be allocated to one of two categories. The first category is “review and assessment” whereby the NIPT and ECG take stock of individual centers’ progress to date and their respective plans for the future as well as make a holistic assessment of the eight centers as a program of research. The following quote was typical of responses from both NIPT and ECG personnel regarding this aspect of the annual meeting:

“Seeing [the centers] all together is a real plus. It gives you a real sense whether this is a strong group or that they need some help. Once you listen to them all one after another, you can’t help but come away with comparative information.”

A few of the center directors also mentioned this as a goal of the annual meeting, though most emphasized the next category of goals.

The second category is “communication and learning” whereby the centers interact and learn about one another’s progress over the past year, and also interact with the NIPT and ECG to elicit feedback regarding their center’s progress and direction. All of the center directors interviewed cited learning about potential collaborations as a goal; they also all cited getting critical feedback from the NIPT (both during the meeting in a closed-door session and in written form, after the meeting) as an important goal.

The goal of critical feedback to the centers was exclusive to the second of the two annual meetings to date. The reason for this was that by the time of the first annual meeting in 2007, the first cohort of centers was just getting started. To facilitate the more evaluative goals of the second meeting in 2008, the NIPT requested that each NDC submit its annual progress report (see Section 4.1 below) a few weeks prior to the annual meeting.

The interview data reveal no variation regarding the attainment of these goals at the annual meetings. Everyone interviewed – NIPT, ECG, and NDC leadership alike – agreed that the all of the meeting goals were met both in 2007 and 2008.

## **2.3. Activities versus goals**

Another purpose of this study is to assess the efficiency of the annual meetings, that is, the identification by participants of discrete activities (e.g., poster session, research presentations) that are perceived not to have helped to fulfill annual meeting goals. The study also assessed the

perception on the part of meeting participants of activities that currently do not occur at the annual meetings “but should” in order to better attain annual meeting goals.

The study was unable to identify any existing annual meeting activities that were not valued by at least some of the participants. What disagreement occurred across the interviews (e.g., with one interviewee valuing an activity and another suggesting that it should be modified) was more a function of emphasizing different goals than was it the result of any participants holding truly divergent views of the activities and goals of the annual meetings.

For example, there was almost universal agreement across the NIPT, ECG, and NDC directors that the “overview” presentations at the beginning of the meetings are useful for facilitating understanding of the program as a whole and also for increasing awareness amongst these groups of potential areas of mutual interest or perhaps even collaboration across the NDCs. From a member of the ECG:

“The talks by the center leadership are useful for getting up to speed, remembering what they are doing and learning where they are headed.”

In contrast, some interviewees suggested that there is a trade-off between these high-level presentations and more detailed scientific interactions. Here is a comment from another ECG member regarding the overview presentations vis-à-vis the relatively evaluative focus of the second annual meeting held at UCSF:

“There’s a lot of presentations at the start that don’t have a lot of depth. Even though the centers provided us with progress reports [before the 2008 annual meeting], the format of the meeting doesn’t allow us as consultants to ask in-depth questions with enough time to keep probing. It runs on a very tight timeframe.”

However, this comment should be discounted, since it was given by an ECG member who had limited participation in the other management and evaluation activities of the NDC program, such as site visits and progress report review and feedback (see Sections 3.1 and 4.1 below). The annual meeting is a complementary component of a suite of oversight and evaluation mechanisms with which the NIPT manages and operates the NDC program.

It should be noted that at the beginning of this study interviewees additionally were asked about the allocation of roles across the NIPT, ECG, and NDC leadership and participants for the annual meeting. The idea was to discern whether the “appropriate” people were performing the “appropriate” activities during the annual meeting – a typical line of inquiry when assessing the strategic management of a program or organization (Condrey 2002). Because questions of this nature yielded no variation (all responded that the allocation of roles seemed correct) and in some instances confusion, they were abandoned after the first interviews.

## 2.4. Perceived value and suggested changes

The final purpose of our examination of the annual meetings was to identify the relative value of each of the meeting activities. The reasoning for this was that as the NDC program matures and the centers become established, there will be more to assess (e.g., productivity, development, clinical tests) in the same timeframe. Accordingly, we also asked about changes to the annual meeting as the program moves forward.

A majority of the interviewees had positive summaries of the annual awardee meetings. For instance:

“I don’t have any criticisms for how the [annual] meetings are arranged. They are good venues. In addition to the oral presentations, there are poster sessions which are quite active. There are plenty of opportunities for engagement.”

When asked about the relative value of the discrete activities of the annual meetings, quite a few interviewees emphasized informal interactions, especially with junior-level participants (post-doctoral students, graduate students, and junior faculty). From a member of the NIPT:

“What is certainly the most fun is the poster session. Then, you get to talk to the students who are actually doing the work. From them, I get the best sense of where things are going. The PIs are pretty polished. It’s nice to actually look at the data on these posters. I don’t talk a whole lot with the center PIs. I try to talk to 1 to 2 levels under that, including post-docs and grad students. I get a feel for where [the center] is from this.”

Other responses across the participant and stakeholder groups interviewed suggest the importance of the NDCs interacting with one another, again informally at the meeting reception and during meals and breaks. All respondents indicated that they valued the annual meeting and that they believed the NIPT was doing a good job running them.

When asked about changes for future annual meetings, those who had suggestions (about half of the interviewees did not, stating they thought the meeting fine as-is) emphasized making the meeting longer and providing more time for smaller-group sessions. From another member of the NIPT:

“There’s a part of me that says the [annual meeting] is too big in terms of who shows up. The centers bring people with them. The format is that you don’t really have time to interact with each other. It doesn’t succeed in what it’s supposed to do. How to improve it? Make the size of the meeting smaller, and increase the time at the meeting, maybe by a day.”

From members of the ECG:

“If I was going to change anything, I would perhaps have some more time for breakout with the individual projects and the team groups here as opposed to full body meetings where everybody is grouped together. That probably occurs a couple of times already. But I would have more time dedicated to small groups. The benefit would be additional time for more detailed feedback. The current format is that there is discussion following the meetings, but there isn’t that immediate feedback with the center directors.”

“The presentations and posters are fine, but we could reduce some of that. They can be great or horrible. Since the point [of the annual meeting] is more than just to transmit information between groups, I really would like presentations just among the senior leadership of the centers and the NIH folks – to talk about where they are on target and where they are not.”

Some of the NDC directors interviewed also suggested a need for smaller-group sessions, but for discussing topics of mutual interest and collaboration rather than for critical feedback. For example:

“The meeting is getting larger and larger. At first there were 4 groups, now there are 8. I think there would be some more time allocated explicitly for joint effort or discussing collaborations. Maybe a small discussion group or multiple groups. Right now we have talks, each center, an hour per center. So that takes a day. And, the poster session takes another half day. So, maybe we should try out some of these discussion groups on topics of general interest [across the NDCs].”

We also asked interviewees whether they thought the awardees should meet more than once per year. There were no affirmative responses. Many contended that once per year is sufficient. Others cited that while meeting more than once per year could be useful, the costs of the additional travel and preparation would probably outweigh the benefits of the extra meeting(s).



### 3. Site visits

The second component of the interviews conducted for this study addressed the site visits in which teams comprised of Nanomedicine Implementation Project Team (NIPT) personnel and Extramural Consultant Group (ECG) participants visit the Nanomedicine Development Centers (NDCs). This section summarizes the findings for this component of the study and is empirical.<sup>4</sup> No quantitative decision rules were used for inclusion or exclusion of the findings. Both unique and common perspectives are presented.

#### 3.1. Brief description

The NIPT assigns teams of NIPT and ECG personnel to oversee the management and progress of each NDC via two chief “mechanisms.” One of these mechanisms is the site visit (the other is the progress report, discussed in Section 4.1). Team visits to centers began in 2006, but have not been regularly scheduled. Team membership is determined by the relevance of the individuals’ scientific and technical expertise to the NDC in question.

**Table 3.1. NDCs visited to date (December 2008)**

<i>Center</i>	<i>Total Visits</i>
National Center for Design of Biomimetic Nanoconductors	3
Cell Propulsion Lab	3
Nanomedicine Center for Nucleoprotein Machines	2
Center for Protein Folding Machinery	1
Center for Cell Control	1
Nanotechnology Center for Mechanics in Regenerative Medicine	3
Phi29 DNA-Packaging Motor for Nanomedicine	1
NDC in Optical Control of Biological Function	1

Frequently, site visits coincide with a center’s internal annual meeting. Accordingly, the structure of the visit generally has been determined by the structure of that meeting, and the visiting teams usually “observe” more than they “participate” during the site visits. Site visits typically last 1-2 days and are comprised of scientific presentations, informal interactions such as poster sessions, and typically a closed door session with the center leadership. Other activities may be organized by the center, such as additional discussion sessions or facility tours.

The chief goal of site visits is to provide feedback and guidance to center leadership. Feedback occurs formally in writing following the site visit and sometimes occurs during the actual visit. The information gathered and opinions formed as a result of site visits are used by the NIPT to inform budget decisions, as described in Section 5.

Following the site visit, the visit team leader drafts feedback based on the collective assessment of the team. This feedback report is presented to the NIPT, after which it is delivered to the center director. Site visit reports have discussed center directors’ management style, the atmosphere and organization of the center meeting, scientific approaches, scientific progress, and the relevance of center direction and goals to the Nanomedicine Initiative. On occasion, center leadership has responded to a site visit team’s feedback.

<sup>4</sup> For a full description of methodology, see Appendix A.

### 3.2. Goals and goal attainment

One of the purposes of this study is to identify variable perceptions of the goals of the site visits, insofar that a lack of clarity in or agreement over goals can lead to “ineffective” use of resources in public programs and organizations (Rainey 2003). The study found evidence that perceptions of the goals of the site visits vary, but are no less aligned around the theme of providing information for decision making.

From the perspective of the NIPT and the ECG, the overarching goal is to acquire additional information about center research and management to inform programmatic budget decisions. From the perspective of NDC directors, the overarching goal is to provide information for programmatic decision making as well as to acquire feedback to facilitate internal decision making regarding center research and management. This study found consensus across these groups that the site visits have fulfilled these goals.

Specifically, the NIPT and ECG personnel interviewed generally characterized site visits as an information gathering and feedback activity. The goal of the additional information is to discern the accuracy of these perceptions and, if proved accurate, to inform funding decisions. A representative comment from an ECG member:

“We use the site visits to reinforce with them that we’re quite serious that they’re not doing what we think they should do, and centrally to document what is going on there in the case that we would need to start to shut them down.”

From a NIPT member about a recent site visit:

“We were going [to visit the center] to decide if they should be completely shut down or given a further ‘probationary’ period.”

The site visits were perceived unanimously amongst the interviewees as successful in providing useful feedback to the visited centers. From an ECG participant:

“[After the site visit,] I was amazed at how they really heard what it was we said. They’ve made a lot of effort to change what it is they are doing more or less in the ways we want them to.”

The NDC directors interviewed perceived the goals of the site visits in precisely the inverse manner – to communicate to the NIPT and ECG how their centers will alleviate perceived problems – sometimes simply by demonstrating how particular negative perceptions are inaccurate, though most frequently to address legitimate concerns of the NIPT and ECG. All of the NDC directors interviewed whose centers have been visited to date expressed this as the primary goal of the site visits. Also, all of the directors interviewed felt the site visits to have been successful in attaining this goal.

Another goal of the site visits identified by the NIPT and also by the ECG members interviewed was to gather information about center interactions, processes, and management that is difficult to glean from annual meeting presentations or progress reports:

“[On site visits] you get to hear in much more detail what is going on and to get a sense of how the groups are interacting. We want them to be as interactive as possible. It allows us to see how well the faculty and post-docs and students are talking to each other. It gives us an indication of how well interactions are taking place.”

“It’s an opportunity to better see all of the things being done at the center. On site visits you are spending more time with people, you get a better idea of how the center operates, how people get along with each other, and if their activities span across multiple laboratories.”

However, not all of the NIPT and ECG members interviewed felt that this goal is always attained on site visits. Specifically, this type of information seems less easily extracted by the site visit teams when the visits coincide with the centers internal annual meetings. This is discussed further in the next sub-section on site visit activities.

### **3.3. Activities versus goals**

Another purpose of this study is to assess the efficiency of the site visits, which we operationalize as the identification by participants of discrete site visit activities (e.g., poster sessions, research presentations) that are perceived not to have helped to fulfill site visit goals. An alternate (inverse) operationalization for this is the perception on the part of site visit participants of activities that currently do not occur during the visits “but should” in order to better attain site visit goals.

In a few of the interviews, it was brought up that timing the site visit with a center’s internal annual meeting is not always an advantage. While it exposes the site visit team to the full membership of the center (e.g., many NDCs are not collocated and therefore must have some of the investigators travel to the meeting), some NIPT and ECG members felt that the formality of these meetings took time away from gathering the information they were interested in. From an ECG member:

“I was a little disappointed in this site visit that they did it top down – they had senior leadership talking too much. I would have wanted to hear more from the people where the science is really happening. The talent in these groups is often in the junior faculty and post-docs. It was more a formal presentation rather than us observing their meeting. It was supposed to be us observing a day-in-the-life, and it became a dog-and-pony show. I wanted to see them exchange some ideas, and to even have an argument or two... It was screwed up from the beginning. They put us in the center of the room and distributed them around us. They heard us when we were leaving say that the next time they hold a scientific meeting and just have us attend.”

Despite this interviewee's disappointment with the structure of the site visit, it was no less perceived as attaining its goals:

“I found it very helpful. It really put [center research and activities] in perspective.”

Some members of the NIPT expressed similar sentiments about the site visits being too formal, though maintained that the site visits have been very successful at informing decision making even when they are more formal than they would like. For example:

“I wish we could just show up [unannounced for site visits], impromptu. If [center leadership] is over-prepared, it becomes more difficult to see how the center operates, how they interact. We already get polish at the annual awardee meeting. Management is a critical component, and it is almost impossible to glean from the annual awardee meeting.”

Along this line, site visits that were less formal were described as beneficial:

“There are times when it would be nice to see more people in their lab environment. I went on one site visit where one center, except for one component, was on campus but in different departments. We were able to visit the investigators in their labs to discuss their work. For some [centers] this isn't possible, since they are spread out. It is beneficial to see the people doing the work.”

However, some of the ECG and also the NDC directors with faculty who are not collocated explained that it is important for the site visits to coincide with their internal annual meetings:

“I think having the site visit coincide with our meeting is good because you get to bring everyone together. A lot of these centers are quite distributed [geographically]. One has people in Switzerland, Israel, and Germany I think. So the site visit has to be in conjunction with the annual meeting. But that's an extreme case. Others are distributed across the country.”

It should be noted that at the beginning of this study interviewees additionally were asked about the allocation of roles across the NIPT and ECG as they participate on site visit teams. The idea was to discern whether the “appropriate” people were performing the “appropriate” activities during the site visits – a typical line of inquiry when assessing the strategic management of a program or organization (Condrey 2002). Questions of this nature were demonstrated to be irrelevant (all responded that there are not discrete roles for members of the site visit team).

### **3.4. Perceived value and suggested changes**

The final purpose of our examination of the site visits was to identify how they are valued by program participants. The reasoning for this was that the NDC program has a number of

mechanisms for interacting with and learning about center management and progress (e.g., the annual awardees meeting, progress reports), and some of the NIPT and ECG members interviewed expressed that they have not had enough time to participate in site visits. Accordingly, we also asked for suggested changes to the site visits as the program moves forward.

All of the ECG and NIPT members interviewed had positive summaries of the site visits. Specifically, they emphasized the importance of observing center leadership, faculty, and other participants (e.g., post-doctoral researchers, graduate students) interact. Many of the quotes above speak to this emphasis. The information they gather at site visits is valued by NIPT and ECG members in that it is unique in comparison to and complementary with the information they gather by way of progress reports (see Section 4) and annual meetings (see Section 2). From a NIPT member:

“Sometimes you get a lot more details in the site visit presentation than you get in the progress report because those have page limits. You can get certain levels of detail. Also, the progress report is usually a little behind. What they present at the site visit is a little more up to date.”

From an ECG member:

“If a group is doing well in its progress reports, the site visits are less important. When a group is having problems, we use feedback from the site visits more. You either confirm the problems you see or you conclude ‘they may be having problems in the progress reports but the site visit clarifies that they are doing okay.’”

The NDC directors interviewed agreed. For example:

“For the site visit, we have everyone in the center present so the program officials can get a sense about the people doing the work, not just of me. So they can see the quality of the center participants who actively engage in our research. Also important is the question and answer after each presentation. This gives the NIH a more accurate assessment of how we work as a team. In contrast, the progress reports are so smooth. Once you have 150 people in a room, you cannot hide. The site visit is the most telling about the progress, the excitement, and the group dynamics.”

“During the site visits we just have meetings where we discuss amongst ourselves, we debate and question ourselves. If a post-doc or faculty member presents, we ask a lot of questions. That type of stuff you can’t put on a progress report. Sometimes we have different opinions...Unless the NIPT is at these meetings, they will not get this sense of how we work.”

All of the ECG and NIPT members interviewed expressed a similar view of the uniqueness of the information gleaned from site visits and how this information complements the annual

meetings and progress reports. During the interviews, however, some saw the site visits as less valuable. From a different ECG member:

“If I were to rank them, I’d say (1) progress reports, (2) annual meeting, and last (3) site visit. I might even reserve site visits for problematic centers. It’s kind of like taking a student aside who is having problems.”

This respondent prefers the annual meeting to the site visits because “it’s like one stop shopping, you get to see them all in a row.” This respondent and others from the NIPT and ECG frequently cited a lack of time to make the site visits (in addition to the annual meeting and participating in progress report review and feedback). However, they still agreed that the information from site visits was important to the overall evaluation of the centers.

All of the study participants valued the direct discussion between the site visit team and center leadership about the progress and future direction of the centers. From an ECG member:

“I think the most valuable aspect of the site visits is to literally be in a room – maybe 15 total, 8 of them and 7 of us – and have a very frank and open discussion of what the issues are. If we’re wrong, they tell us we’re wrong. It’s a very open give-and-take. [The centers’ leadership] realize that we are not there to shoot them down, but to understand what the issues are and maybe to help them.”

Very few of the interviewees had suggestions for improving the site visits. We asked whether they thought the site visits should be regularly scheduled. There were no affirmative responses. Many contended that visits should be reserved for “problem” centers. Their reasoning was that the time of NIPT and ECG members is valuable and that it should be used only for site visits that have evaluative implications. To the extent that this study can tell, the site visits started out as mechanisms to use regardless of how a center is performing but have been limited more recently by the NIPT – which is acutely aware of the time constraints its members and the ECG are under – to problematic centers.

## **4. Progress report review and feedback**

The third component of the interviews conducted for this study addressed the progress reports submitted by the Nanomedicine Development Centers (NDCs) and reviewed by teams comprised of Nanomedicine Implementation Project Team (NIPT) personnel and Extramural Consultant Group (ECG) participants. This section summarizes the findings for this component of the study and is empirical.<sup>5</sup> No quantitative decision rules were used for inclusion or exclusion of the findings. Both unique and common perspectives are presented.

### **4.1. Brief description**

Each NDC must submit a progress report annually to the NIPT. For 2008, the due date for the report was moved from after to before the annual awardee meeting, to facilitate the evaluative purpose of that meeting (see Section 2 above). The progress report for each NDC is reviewed by the same team of NIPT personnel and ECG participants who are responsible for the site visits (if any) for that NDC.

The progress report contains several different types of information and resembles a typical progress report. Budget information for the next year, scientific progress, future plans, training, collaborations, and a list of publications are some of the sections which may be included. In addition to these standard types of content, the purposes for which set aside funds were used may be discussed.

The progress report serves several purposes. First, it constitutes formal codification of the progress and plans of each NDC. Second, it is used to inform program budget decisions. Finally, it is used as an opportunity to provide feedback to the centers. The center directors additionally view the progress report as an opportunity for internal assessment.

Before the progress reports are due, the NIPT releases instructions to the center directors. The instructions have typically requested 8-15 pages of scientific progress, plans, the intended use of set aside funds, collaborations, training, management concerns, and publications. Another 2-3 pages were an executive summary of the center which was then posted on the Nanomedicine website. As described in Section 5, the 2007 progress report was submitted with proposals for use of set aside funds.

Once the progress reports are received by the NIPT, they are reviewed by the teams consisting of NIPT and ECG personnel who are assigned to the centers (as described for the site visits in Section 3). Each team member uses review criteria to assess the center. The leader of each team then synthesizes team members' comments to form a coherent document. This document is presented at a meeting of the NIPT by the team leader before being delivered to the center. Occasionally, centers have responded in writing to progress report feedback.

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<sup>5</sup> For a full description of methodology, see Appendix A.

## 4.2. Goals and goal attainment

One of the purposes of this study is to identify variable perceptions of the goals of the progress reports, insofar that a lack of clarity in or agreement over goals can lead to “ineffective” use of resources in public programs and organizations (Rainey 2003). The study found evidence that perceptions of the goals of the progress reports are consistent across the NIPT, ECG, and NDC directors, aligned around the theme of relatively formal assessment (i.e., in comparison to the annual meeting and the site visits).

From the perspective of the NIPT and the ECG, the overarching goal is to document progress of center research towards and the alignment of future research with the goals of the Nanomedicine Initiative. From a NIPT member:

“The progress reports are important from a documentation point of view. It’s a formal record of what has happened [for a particular center]. It helps us see what the center has achieved for the millions of dollars we have given them. When you ask what the center has achieved, that’s when you pull out the progress report. Importantly, it lists publications and whether they were completely supported by the program.”

An ECG participant adds that the progress reports may have more weight than other mechanisms when it comes to informing decisions about budget:

“The goals of the progress report are a bit more formal. This is the assessment of their progress that is going in the official file. It is used more for future funding decisions than the site visits are... because the information is being provided in a way that is captured more formally. In the site visits, a lot of interactions and discussions are informal and not written down. When you have something on paper it is more easily captured into your decisions.”

However, the discussion of site visits above (see Section 3) suggests that site visits – which actually are codified by a report at the end from the site visit team – can be very influential in budget decisions for centers perceived as having problems.

In addition to tracking progress, another goal of the progress reports is to track the research trajectory of the center and any changes made as the center progresses.

“[The progress report] also documents if things have changed. If [the center] decides that a specific aim isn’t going to work, the progress report explains why and what they’re going to try now.

The NDC directors interviewed made similar comments about the importance of the progress reports being the codification of center output and direction for communication to the NIPT. Additionally, they perceived “self-assessment” as a goal the process of collecting the information for the progress reports. For example:



“One goal is to see for myself where I have been. We have 11 different investigators. The progress report is one way for us to develop a comprehensive look at where we have been in the last 12 months. [Developing the report] gets everybody engaged and they tell me what they have done and they propose what they will be doing. It is a good mechanism to get everybody recharged and to think a little bit.”

Another goal of the progress reports is for the NIPT and ECG to provide feedback to the centers. In all interviews but one, NDC directors suggested that the feedback they received was helpful for center planning. A typical remark:

“[The feedback] is good. It’s good to tell the investigator that they are on the right or wrong track. Keep in mind that [this process] is very different from a regular research grant. It is very important for [the NIPT] to comment on where they want us to go.

In one interview with an NDC director, the remarks about the progress report feedback received were negative. This director felt that the progress report was misinterpreted and misunderstood. Accordingly, a site visit was scheduled. After the visit, the center director reported that the meeting went “surprisingly well” and that the NIPT and ECG had a better understanding of the center’s progress and relevance to the Nanomedicine Initiative. This director also reported having developed a greater appreciation for the expectations of the NDC program.

### **4.3. Activities versus goals**

Another purpose of this study is to assess the efficiency of the progress report, which we operationalize as the identification by participants of discrete elements of the progress reports that are perceived not to have helped to fulfill goals. However, the interviews revealed no perceived problems with the progress report review and feedback processes.

It should also be noted that at the beginning of this study interviewees additionally were asked about the allocation of roles across the NIPT and ECG as they participate in progress report review and feedback. The idea was to discern whether the “appropriate” people were performing the “appropriate” activities during the processes – a typical line of inquiry when assessing the strategic management of a program or organization (Condrey 2002). Questions of this nature were demonstrated to be irrelevant (all responded that there are not discrete roles for members of the progress report team, but rather that they act collectively “as a panel”).

### **4.4. Perceived value and suggested changes**

The final purpose of our examination of the progress report review and feedback processes was to identify how they are valued by program participants. The reasoning for this was that the NDC program has a number of mechanisms for interacting with and learning about center management and progress (e.g., the annual awardees meeting, site visits). Accordingly, we also asked for suggested changes to the progress report processes as the program moves forward.

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All of the ECG and NIPT members interviewed had positive summaries of the progress reports as part of a broader suite of program management mechanisms. Specifically, they emphasized the formalness of the progress reports and how this complements the information gathered on site visits and during the annual meeting. From NIPT and ECG members:

“Because [the progress reports] are written out it’s a lot easier to digest than a site visit or annual meeting. You can go over it multiple times and they have references and figures. While the reports are long and often I am pressed for time, I’m glad to do it.”

“The progress reports are different than the site visits and annual meeting. There’s only so much that can be put on the pages and digested. There’s not opportunity for questions and answering. But the progress reports are important because they’re records.”

Many NIPT and ECG respondents reported valuing the progress reports because they help to indicate which centers need to have a site visit and which do not. But again what they valued most was the documentation of center activities. A typical remark:

“[The progress report] becomes much more important if you have a ‘troublesome’ center. To go to them, to take action against them, you need firm documentation to back it up, to show you are being fair. It’s a paper trail. It’s still important to have for the ‘good’ centers as well, but not as important.”

The interviews solicited almost no recommendations for improving the progress report review and feedback processes. The only suggested change was given by an ECG member who reported that time was a constraint to participation. This member suggested measures to facilitate progress report review and comparisons across the NDCs:

“[Each of the NDCs] use different formats [for the progress reports]. They need to be standardized. I know they’ve been given recommendations of what should be included, but they don’t seem to have listened. They need to have a template to fill out. Right now the reports are free-flowing. With a template it would be easier to evaluate and compare the centers.”

## 5. Budget management and set-aside funds allocation

The fourth component of the interviews conducted for this study addressed budget management and set-aside funds allocation. This section summarizes the findings for this component of the study and is empirical.<sup>6</sup> No quantitative decision rules were used for inclusion or exclusion of the findings. Both unique and common perspectives are presented.

### 5.1. Brief description

The Nanomedicine Development Centers (NDCs) have a number of sources of NDC program funding. First, they receive base funding annually. Base funding was \$1.4 million per NDC during the initial year of the program and has been \$1.2 million per NDC each year since (see Table 5.1).

**Table 5.1. Base funding for the NDCs (total cost), 2005-2008**

<u>Center</u>	<u>2005</u>	<u>2006</u>	<u>2007</u>	<u>2008</u>
Center for Protein Folding Machinery	\$1,400,000	\$1,200,000	\$1,200,000	\$1,200,000
National Center for Design of Biomimetic Nanoconductors	\$1,400,000	\$1,200,000	\$1,200,000	\$1,200,000
Cell Propulsion Lab	\$1,400,000	\$1,200,000	\$1,200,000	\$1,200,000
Nanotechnology Center for Mechanics in Regenerative Medicine	\$1,400,000	\$1,200,000	\$1,200,000	\$1,200,000
Nanomedicine Center for Nucleoprotein Machines		\$1,200,000	\$1,200,000	\$1,200,000
Phi29 DNA-Packaging Motor for Nanomedicine		\$1,200,000	\$1,200,000	\$1,200,000
Center for Cell Control		\$700,000	\$700,000	\$700,000
NDC in Optical Control of Biological Function		\$1,200,000	\$1,200,000	\$1,200,000

A center's base funding may be enhanced or scaled-up as the NIPT decides. An NDC may also have its base funding decreased or scaled-back by the NIPT. While there have been instances of budget scale-ups, there have been no incidences in which the NIPT has chosen to decrease an NDC's annual funding to lower than the base rate.

In addition to base funding, a portion of the program's funds are set aside and distributed at the discretion of the NIPT. The purposes to which set-aside funds have been distributed have varied from year to year, depending on perceived need by the NIPT and ECG. In some years, each NDC has received set-aside funds in a non-competitive allocation. In other years, set-aside funds have been allocated by way of a limited competition amongst the NDCs.

**Table 5.2. Set-aside funding for the NDCs, 2005-2008**

<u>FY</u>	<u>Amount of set aside funding</u>	<u>Set aside funds as % of total in that year</u>
2005	\$0	0%
2006	\$800,000	7.7%
2007	\$3,212,887	25.1%
2008	\$1,280,905	11.8%

<sup>6</sup> For a full description of methodology, see Appendix A.

In 2006, a total of \$800,000 was available to distribute as set aside funds to the four centers. The NIPT asked the NDCs to submit proposals for how they would use additional funds in varying amounts from \$100,000 to \$400,000, with appropriate justifications for each level. The NDC leadership, the NIPT, and the ECG all met to present and discuss the proposals.

Afterwards, the NIPT decided to allocate the available funds equally across the first cohort of centers, giving \$200,000 to each, concluding “that there was strong justification for elements of each of the NDC requests with no compelling weaknesses” [*FY2006 Set-aside Funding Plan*]. The NIPT did express opinions on how to prioritize some of the options above others, e.g. suggesting that some of the larger ticket items be partially funded via other sources of funds.

In 2007, set aside funds were used for three purposes. First, it was decided by the NIPT that the second cohort should also be eligible for \$200,000, provided that the center directors could provide justifications. Upon receiving the proposals, the NIPT provided feedback to the directors, requesting a greater level of specificity and detailing other changes to make. The center directors then resubmitted their proposals. The NIPT funded the four centers of the second cohort at \$200,000 each (table 5.3).

Second, in an effort to augment the clinical aspect of the NDCs, the NIPT provided \$100,000 to each NDC to “develop [their] clinical interactions” [*NDC Supplement – April 2007*]. The NIPT requested that each center incorporate clinical investigators into the NDC as participants and external advisors.

Third, using the remaining set aside funds available that year, the NDCs were invited by the NIPT to submit proposals. Collaborative proposals including two or more NDCs could request up to \$600,000. Each NDC was allowed to participate in a maximum of two inter-NDC collaborations. Non-collaborative proposals could request up to \$400,000. In response, each of the NDCs requested additional funds, which occurred in the 2007 progress reports. Of these requests, three were collaborative and eight were single-center requests. Four of the individual requests and one of the collaborative requests received the additional funding.

**Table 5. 3. Allocation of NDC program set-aside funds in 2007**

<u>Center</u>	<u>Initial set aside allocation</u>	<u>Pathway to Medicine supplement</u>	<u>Final competitive allocation</u>
Nanomedicine Center for Nucleoprotein Machines	\$200,000	\$100,000	\$250,000
Phi29 DNA-Packaging Motor for Nanomedicine	\$200,000	\$100,000	\$0
Center for Cell Control	\$200,000	\$100,000	\$150,000
NDC in Optical Control of Biological Function	\$200,000	\$100,000	\$512,887
Center for Protein Folding Machinery		\$100,000	\$350,000
National Center for Design of Biomimetic Nanoconductors		\$100,000	\$0
Cell Propulsion Lab		\$100,000	\$350,000
Nanotechnology Center for Mechanics in Regenerative Medicine		\$100,000	\$0

In FY2008, set-aside funds were used to incentivize collaborations between clinicians and the NDCs. The application process for these funds had two steps: letters of interest in collaboration (LICs) from clinicians followed by full applications.

Clinical researchers who were not affiliated with the NDC program were invited to submit letters expressing interest in collaborating with one or more of the NDCs. The letters of interest were to include an abstract, the background of the issue addressed, the current research program of the clinician, the proposed research, the specific nature of the NDC collaboration, milestones and timelines, and CVs.

In total, 34 clinician letters were received, and the NIPT asked the center directors to evaluate the submissions' relevance with respect to their own NDCs. Of the 34, in total the NDC directors deemed 25 as relevant. From these 25, the NIPT then invited 12 clinicians to submit a full application written conjointly with an NDC director. The maximum request was set at \$500,000.

The NIPT and ECG evaluated the full proposals. They decided that two of the NDCs “were not in a position to expand and immediately need to reorganize work and possibly personnel at their center to better match the goals of the NDC with the Nanomedicine initiative goals” [*FY2008 Set-Aside/Scale-up Funding Plan Part 1- Clinical Collaborator Supplements*]. The remaining NDCs had 10 proposals among them. Of these, four NDC-clinician collaborations were approved and set aside funds were allocated as below.

**Table 5.4. FY 2008 clinical collaborator applications for set-aside funds, per NDC**

<u>NDC</u>	<u># of applications</u>	<u>Funds approved</u>
Nanomedicine Center for Nucleoprotein Machines	1	\$0
Phi29 DNA-Packaging Motor for Nanomedicine	1	\$0
Center for Cell Control	2	\$500,000
NDC in Optical Control of Biological Function	2	Funds approved but not released
Center for Protein Folding Machinery	3	\$337,700
National Center for Design of Biomimetic Nanoconductors	1	\$0
Cell Propulsion Lab	1	\$0
Nanotechnology Center for Mechanics in Regenerative Medicine	1	\$443,205
Total	12	\$1,280,905

## 5.2. Perceptions of overall budget management

One of the purposes of this study is to identify how participants perceive the purposes for which program funds have been expended. In this sub-section we present findings regarding overall budget management. In the next sub-section, set-aside funds allocations are discussed.

Originally, this study aimed to discern the “rationale” for distributing funds across the NDCs. However, responses to this line of questioning revealed little variation and a level of generality

that provided little insight. Responses were positive, including “to fund the best science” and “to meet program objectives.”

Next, we asked about stakeholder perceptions of the “fairness” and “appropriateness” of program budget management. All of the interviewees believed the NIPT to be allocating funds fairly and appropriately. Typical remarks from NIPT and ECG members included:

“Decisions of what funds have been used for have been made fairly. It is a collective decision from the [NIPT]. While not everyone agrees all of the time, everyone agrees in the end that they can live with the decisions.”

“The funds have been very appropriately allocated. I’ve proposed some things which haven’t gone through, but I think the system by which decisions are made is fair and brings in a variety of expertise.”

“My answer is that it is just fine... Given the circumstances, the [budget related] choices which have been made [by the NIPT] are excellent. ”

While a couple interviewees from the ECG expressed worry about the allocation of NIH funds towards “nontraditional” projects, they no less remained positive regarding the budget management practices of the NIPT. For example:

“I think [the budget management of the NIPT] has been fine. This seems to me, as an outsider, an experiment within the NIH. The NIH knew there would be this strange dichotomy within the program of fundamental science versus clinical research... I worry about making [the centers] interact with clinicians.”

The same ECG member also expressed concern over the difficulty of scaling back the funds, suggesting that the NIPT should be more willing “to pull the plug” on centers that seem to be underperforming:

“It’s like a poker game. There are a lot of chips on the table and everyone’s afraid to fold their hand. The feeling is that there’s all of this money, and if it goes unused it’s wasted. But so what? It’s better to take it back than to waste it. Don’t send good money after bad.”

Another ECG member who expressed concern about scaling back funds recognized that the NIPT has acted appropriately by not scaling back the funds of “problem” centers at this stage in the program:

“I think the [the NIPT] is using the power [to increase or scale back funds] at least as much as it should. It’s really hard to scale back some of these centers because they show promise. It’s hard to cut them down before they have a full chance to get things going. The NIPT has really done a good job...”

Taken together, the qualitative results strongly suggest that the ECG and NIPT perceive that overall budget management by the NIPT has been both fair and appropriate.

### **5.3. Perceptions of set-aside funds allocation**

The use of set-aside funds is generally perceived by NIPT, ECG, and NDC participants as “effective.” The many positive remarks made by study participants include this one from a member of the NIPT:

“It has been just a godsend. The program for the clinical collaborators did exactly what we wanted it to do. The centers didn’t have MDs involved, but they’ve got them now. It worked like a charm. I was surprised and delighted that it worked as well as it did. But maybe I’m naïve. I was concerned that the basic scientists [at the centers] would be much more resistant to the clinical world

Most of the ECG members interviewed made comparably positive remarks about the use of set-aside funds. However, the ECG members who expressed concern about willingness to scale back center funds (see above) also expressed concern over the use of set-aside funds. The first ECG member had a problem with the use of funds for clinical collaborators:

“I feel like the set-aside funds should have been put more rationally towards a science direction, rather than getting them to the clinic. If [the centers] found an area [of science] where they were weak or needed to move into quickly, they could use the money for that.”

The second ECG member, however, recognizes the difficulty of allocating set-aside funds:

“The set-aside funds are a funny thing. I’m torn on how I think about those. They’re very difficult to decide how to award them. The centers are underfunded to begin with. But the centers that are doing well [with base funding] are also those who do well in their requests for additional [set-aside] funding. Certainly, the process has been thorough. But the proposals [for set aside funds] that are submitted, because they are limited to a small group, are always a bit disappointing in their content.”

In addition, numerous interviewees expressed interest in seeing the set-aside funds put to other purposes. A notable recommendation was to use some of the funds for “informatics infrastructure” whereby a common database tracking project data and results across the NDCs would be constructed for common access and use across the NDC program.

Another notable recommendation was to use set-aside funds to broaden the investigators involved with the centers. From a NIPT member:

“One potential use which we’ve discussed as potentially useful is to use set-aside funds to bring in outside investigators more. We’ve done that with clinical

investigators but potentially we could set aside some funds and earmark them for bringing in new basic science collaborators.”

A last recommendation of note suggested a needs-based approach for determining set-aside funds amounts and recipients. From an ECG participant:

“If we [allocated set-aside funds] more on a problem-based approach, rather than a clinic-based approach, that would be good... Because, for a number of the centers, I’ve seen that the roadblocks they face are scientific and they do not have the funds to get around it. I’d make the set-aside funds more problem-centered.”

To be clear, the perceptions reported here constitute those of the study participants and not of the evaluation team. Taken together, the qualitative results strongly suggest that set-aside funds allocation has been appropriate, though there are some ideas for the purposes to which future allocations should be put.



## 6. Perceptions of the NIPT and the ECG

After discussing with each study participant the discrete mechanisms used by the Nanomedicine Implementation Project Team (NIPT) to manage and oversee the Nanomedicine Development Centers (NDCs), the interviews were concluded with general questions about perceptions of the NIPT, its use of resources, and suggestions for improvement as the program progresses. This section summarizes the findings for this component of the study and is empirical.<sup>7</sup> No quantitative decision rules were used for inclusion or exclusion of the findings. Both unique and common perspectives are presented.

### 6.1. Span of expertise

The goals of the NDC program require that academic researchers with a variety of disciplinary backgrounds and training interact and collaborate with one another. Accordingly, for the NDCs to be managed and evaluated appropriately, the NIPT and ECG collectively require expertise in areas of scientific and clinical research that are relevant to the research activities of the eight NDCs.

In a series of interviews, we asked NIPT personnel, ECG participants, and NDC directors about their perceptions of the “span” of expertise represented by the NIPT and by the ECG. Interviewees were not asked about the expertise of their same-group colleagues. For instance, ECG participants were asked about their perceptions of the NIPT, while NIPT personnel were asked about the ECG. NDC directors were also asked about their perceptions of the teams of ECG participants and NIPT personnel with whom they interact at the annual meetings, during site visits, and during the progress report review and feedback process.

Generally, all respondents indicated that the NDC program is appropriately staffed in terms of expertise. For example, the majority of responses by ECG participants and NDC directors to the question “Are there areas of expertise not represented by the NIPT roster that should be?” were short responses such as “No, I think the NIPT covers all of the important areas.” This characterization also applies to responses to the same question about the span of expertise represented by the ECG. For instance, practically all of the NIPT personnel interviewed reported that the ECG is appropriately staffed in terms of expertise. In contrast, one member of the NIPT mentioned that the ECG “has some ‘nano’ expertise but not enough.”

An important theme that developed from this line of questioning was the time constraints of program participants. For example, from a member of the NIPT:

“I think with the full roster, the NIPT covers a pretty broad area. The real problem is that we can’t always get the people we need involved at a particular time because everyone has so many other commitments. In theory, we have the coverage we need, but in practice we can’t always get who we need.”

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<sup>7</sup> For a full description of methodology, see Appendix A.

The issue of time is recurrent throughout this report and is summarized in the Executive Summary.

## **6.2. Use of resources and suggestions for improvement**

Study participants were also asked about their perceptions of the NIPT's use of resources, broadly defined (e.g., time, funds). Specifically, ECG participants and NDC directors were asked "Is the distribution of program resources (e.g., money, time) across the post-award activities of the NIPT appropriate?" As with the question about the span of expertise across NIPT personnel (see above), this question elicited brief yet affirmative responses. All of the interviewees reported perceiving the NIPT to be handling program resources appropriately.

ECG members were then asked about any suggestions they might have regarding the NIPT's management and oversight of the eight NDCs as the program moves forward. Very few respondents had suggestions. Most replied with general and positive characterizations of the NIPT. Here is a sample of the responses:

"I'm pretty impressed [with the NIPT]. I don't have any real suggestions [for how they can improve]."

"They're doing a superb job... They've been insightful... I could not be more impressed with their ability to know what the program is trying to do and to make it happen."

"The NIPT has done a really good job of 'close management.' They've used [Flexible Research Authority] in an effective way... I would just say that from what I see, they put a lot of time and effort into this. I think they're doing a really great job in using resources to steer centers in the vision of what the program is trying to be... I can't think of what they could be doing to improve it."

## Appendix A: Methodology

Study methods were predominantly qualitative. Study data came predominantly from interviews, though program documentation was used when relevant and available.

### Semi-structured interviews

The predominant empirical basis of this study was comprised of data collected during a series of semi-structured interviews with Nanomedicine Implementation Project Team (NIPT) officials, Extramural Consultant Group (ECG) members, Nanomedicine Development Center (NDC) principal investigators. The interviews were designed to elicit information sufficient to generate a detailed description of post-award management and operation activities using the descriptive and assessment study questions (see Appendix C).

### Interviewee selection

The plan was to interview every member of the NIPT and the director of each NDC, although some were not available. ECG members were interviewed upon recommendation by the NIPT. The target number of interviews was 25-30, depending on the availability and willingness of potential interviewees.

### Soliciting the interviews

The interviews were solicited via email. The template used for the email solicitations:

Dear ...,

At the request of the NIH, the Science and Technology Policy Institute (STPI) is conducting a study examining the management and operations activities of the Nanomedicine Development Centers program since awarding the centers in 2005 and 2006. The study will focus on site visits to the NDCs, the annual awardees meetings, the evaluation of progress reports from the NDCs, and budget management.

Because of your involvement in one or more of these processes, we are writing to ask for your participation in this study, which entails a 30-45 minute discussion to occur sometime in the next two to three weeks. With your help, the study will inform the future activities of NDC program leadership.

In your response, please indicate your date and time preference for the interview. In addition, be sure to include a contact phone number.

Know that your input is invaluable for us providing recommendations in our final report. All information from the interview will be kept anonymous and confidential, analyzed within the STPI and only shared with the NIH in summary form.

We look forward to speaking with you.

Regards,

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In the case of non-response, subsequent emails of a more personalized nature were sent.

### **Constructing the interview protocols**

The STPI team developed numerous interview protocols, the questions contained in each dependent upon which post-award activities interviewees participated in and also on the nature of their participation (i.e., NIPT official, NDC director, ECG member). The interviewee-specific protocols were constructed using a master cache of interview questions developed to address the overarching study questions discussed above.

It should be reiterated that the study questions introduced above did not constitute the interview questions. However, each of the study questions were operationalized by one or more interview questions, some of which were worded similarly to the relevant study question, others not so similarly. The interview protocols (shown in Appendix B) generally included questions that probed at a much finer level of detail than the study questions.

To facilitate cross-sectional analysis of the interview responses, interviewees in the same stratum were interviewed using the same or a very similar interview protocol. NIPT members who participated in the same activities were asked the same questions, as were ECG members who participated in the same activities, as were NDC principal investigators. Some of the interview questions were used for participants across strata. For example, NIPT members, ECG members, and NDC directors were asked about the extent to which the site visits are deemed “valuable.”

Each interview protocol was designed to facilitate “semi-structured” discussions comprised of open-ended questions and responses.

### **Implementing the interviews**

The interviews lasted from 30 to 45 minutes and were conducted over the telephone. Two members of the STPI team participated in each interview – one to conduct or lead the interview and the other to type notes. The interviews were not recorded.

<i>Interviewee stratum</i>	<i>Number of interviews planned</i>	Number of interviews conducted
NIPT Chair	2	1
NIPT	15	12
NDC PI/Director	8	7
ECG	4-8	6
Totals	29-33	26

### **Collating and coding the interviews**

After each interview, the notes were cross-checked by the primary interviewer to ensure accuracy. Once all of the interviews were completed, the responses were collated by interview guide question to facilitate interview data coding and analysis. After collation, the responses to each question were coded, or separated into “bins,” to facilitate the analysis.

### **Document analysis**

There were three types of process documentation that were used to inform the study: deliverables from the NDCs (to the NIPT), deliverables from the NIPT (to the NDCs), as well as procedural documentation:

1. **NDC deliverables.** NDC deliverables entail the progress reports provided to the NIPT annually.
2. **NIPT deliverables.** NIPT deliverables entail the feedback provided to the NDCs after the site visits as well as the feedback provided to the NDCs in response to the progress reports.
3. **Procedural documentation.** Procedural documentation includes meeting minutes, meeting agendas, and guidelines and instructions.

## Appendix B: Discussion guide

This section includes the master cache of interview questions used to develop interview guides. The questions were designed to help answer the study questions outlined at the outset of this study. For each interview, questions were selected and modified based on the group (e.g., Nanomedicine Implementation Project Team [NIPT], Extramural Consultant Group [ECG]). Accordingly, not all questions were used in all interviews. Further, these questions evolved as the study progressed. For transparency, the interview questions are reproduced here as originally drafted.

The interview questions are in regular font. Instructions for the interviewer are capitalized.

### Annual Awardee Meeting Interview Questions

1. Have you attended any of the annual awardees' meetings?
  - a. If no, skip to next section.
  - b. If yes, which ones?
    - i. PROBE IF THEY ATTENDED SOME BUT NOT ALL: Why did you miss some of the meetings?
2. From your perspective as a member of <INSERT AFFILIATION HERE (I.E., AN NDC, THE NIPT, THE ECG)>, what would you say the goals of the annual meetings are?
  - a. PROBE To learn about center progress and about how they are furthering the Initiative?
  - b. PROBE To provide critical feedback to the centers?
  - c. PROBE To inform centers of the potential for budget scale ups or scale backs?
3. From your perspective, were the goals of each of the annual awardee meetings as you just described them achieved?
  - a. PROBE Which of the goals you just mentioned were achieved?
  - b. PROBE Which were not?
    - ii. PROBE Why do you think some goals were not met?
4. What do you think should be different about the annual meeting goals?
  - a. PROBE Which of the goals you just mentioned should be modified?
  - b. PROBE Which of the goals you just mentioned should be deleted?
  - c. PROBE Should any new goals be introduced?
  - d. GENERAL PROBE FOR A-C Why?
5. What specifically did you do at the meetings?

- a. PROBE What activities did you participate in?
  - b. PROBE With whom did you interact? Describe the interactions.
6. How do you think the activities you participated in helped to achieve the goals you mentioned earlier?
- a. PROBE Should existing activities be modified?
  - b. PROBE Should new activities be added?
  - c. PROBE Should any activities be deleted?
  - d. GENERAL PROBE FOR a thru c How will these changes help to achieve the goals you mentioned earlier?
7. What is the value of the meeting for you as a member of the <INSERT AFFILIATION HERE (I.E., AN NDC, THE NIPT, THE ECG) HERE>?
- a. PROBE What do you think the most valuable aspect of the meeting?
  - b. PROBE Least valuable?
  - c. PROBE What do you think can be improved? How?

**Site Visit Interview Questions: ASK NDC about centre meeting structure...**

1. You have participated in site visits to <INSERT NDCs VISITED HERE>, correct?
  - a. If s/he has not participated in any NDCs, skip to next section.
2. From your perspective as a member of <INSERT AFFILIATION HERE (I.E., AN NDC, THE NIPT, THE ECG)>, what would you say the goals of the site visits are?
  - a. PROBE To learn about center progress and about how they are furthering the Initiative?
  - b. PROBE To provide critical feedback to the centers?
  - c. PROBE To inform centers of the potential for budget scale ups or scale backs?
  - d. PROBE How are these goals different than those for the annual awardees' meetings?
3. From your perspective, were the goals of the site visits you participated in (as you just described them) achieved?
  - a. PROBE Which of the goals you just mentioned were achieved?
  - b. PROBE Which were not?
    - i. PROBE Why do you think some goals were not met?
4. What do you think should be different about the site visits?
  - a. PROBE Which of the goals you just mentioned should be modified?

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- b. PROBE Which of the goals you just mentioned should be deleted?
  - c. PROBE Should any new goals be introduced?
  - d. GENERAL PROBE FOR A-C Why?
5. Should the site visits be regularly scheduled?
- a. PROBE With each NDC visited once a year? To coincide with each NDC's annual meeting?
  - b. PROBE Focused not just on "problem" centers but on all of them?
6. What specifically did you do during the site visits?
- a. PROBE What activities did you participate in?
  - b. PROBE With whom did you interact? Describe the interactions.
  - c. PROBE Are the activities the same across the NDCs you've visited?
7. How do you think the activities you participated in helped to achieve the goals you mentioned earlier?
- a. PROBE Should existing activities be modified?
  - b. PROBE Should new activities be added?
  - c. PROBE Should any activities be deleted?
  - d. GENERAL PROBE FOR A THRU C How will these changes help to achieve the goals you mentioned earlier?
8. Is the membership of the site visit teams that you have participated in "appropriate?"
- a. PROBE Do you feel like you provided unique perspective or expertise vis-à-vis your site visit team colleagues? What was the complementarity of perspective or expertise amongst you and your site visit team colleagues?
  - b. PROBE Should membership be more diverse, with some members being quite familiar with the projects performed by an NDC and other members less so?
9. What would you like to be able to do on site visits that you have not done?
10. What is the value of the site visits for you as a member of the <INSERT AFFILIATION HERE (I.E., AN NDC, THE NIPT, THE ECG) HERE>?
- a. PROBE What do you think the most valuable aspect of the site visit?
  - b. PROBE Least valuable?
  - c. PROBE What do you think can be improved? How?

**Progress Report Review and Feedback Interview Questions**

1. You have participated in progress report reviews as a member of the <INSERT NDCs VISITED HERE>, correct?



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- a. PROBE How many? Which ones? The ones for which you are on site visit teams?
  - b. If s/he has not participated in any progress report reviews, skip to next section.
2. Who else has reviewed the progress reports that you have reviewed? Is it the same people with whom you serve on the site visit teams?
3. Is the membership of the progress report review teams that you have participated in “appropriate?”
  - a. PROBE Do you feel like you provided unique perspective or expertise vis-à-vis your REVIEW team colleagues? What is the complementarity of perspective or expertise amongst you and your REVIEW team colleagues?
  - b. PROBE Should membership be more diverse, with some members being quite familiar with the projects performed by an NDC and other members less so?
4. From your perspective as a member of <INSERT AFFILIATION HERE (I.E., AN NDC, THE NIPT, THE ECG)>, what would you say the goals of the progress reports and feedback are?
  - a. PROBE To learn about center progress and about how they are furthering the Initiative?
  - b. PROBE To provide critical feedback to the centers?
  - c. PROBE To inform centers of the potential for budget scale ups or scale backs?
  - d. PROBE How are these goals different than those for the annual awardees’ meetings and the site visits?
5. From your perspective, were the goals of the progress reports you reviewed (as you just described them) achieved?
  - a. PROBE Which of the goals you just mentioned were achieved?
  - b. PROBE Which were not?
    - i. PROBE Why do you think some goals were not met?
6. What do you think should be different about the progress report submission and feedback processes?
  - a. PROBE Which of the goals you just mentioned should be modified?
  - b. PROBE Which of the goals you just mentioned should be deleted?
  - c. PROBE Should any new goals be introduced?
  - d. GENERAL PROBE FOR A-C Why?
7. What specifically did you do during the review and feedback processes?
  - a. PROBE What activities did you participate in?

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- b. PROBE With whom did you interact? Describe the interactions.
  - c. PROBE Are the activities the same across the NDCs you've reviewed?
8. What would you change about the progress reports, the feedback?
9. What do you think about the content of the progress reports you have reviewed?
- a. PROBE What elements of the NDC can be addressed but are not? Is this a function of the instructions provided to the NDCs?
  - b. PROBE Should the progress reports address areas other than the science? Like management and organization?
  - c. PROBE Do the progress reports provide sufficient information for making budget decisions?
  - d. PROBE What do you learn from the progress reports that you do not learn at the Annual Awardees Meeting or the site visits?
  - e. PROBE Could the progress reports be used in aggregate to identify potential synergies across NDCs
10. What is the value of the progress report review for you as a member of the <INSERT AFFILIATION HERE (I.E., AN NDC, THE NIPT, THE ECG) HERE>?
- a. PROBE What do you think the most valuable aspect of the review?
  - b. PROBE Least valuable?
  - c. PROBE What do you think can be improved? How?

**Budget Management (General and Set-Aside) Interview Questions**

1. What is the rationale for the distribution of funds (including scale ups, scale backs, and set aside allocations) across the NDCs?
- a. PROBE "Furthering the Nanomedicine Initiative," even if this means taking funds from some NDCs and giving more to others?
2. Are there other purposes to which set-aside funds could have been put to but have not been?
- a. PROBE How would these additional purposes help to fulfill the goals of the Initiative?
  - b. PROBE Do these additional purposes supplant or complement existing purposes for set-aside funds?
  - c. PROBE Has there been disagreement over how to use set-aside funds?
3. Is the process of general budget management "appropriate?"
- a. PROBE Which of the activities discussed thus far has the most "weight" in terms of budget decisions?

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- b. PROBE Has there been disagreement over budgetary scale-up or scale-backs?
- c. PROBE Could the activities that inform allocation decisions evaluate different or additional criteria? Such as management and operations?

**Portfolio-Level Interview Questions**

1. Are there areas of expertise not represented by the NIPT roster that should be?
  - a. PROBE What areas?
  - b. PROBE Why?
2. Are there areas of expertise not represented by the ECG roster that should be?
  - a. PROBE What areas?
  - b. PROBE Why?
3. Is the distribution of program resources (e.g., money, time) across the post-award activities of the NIPT appropriate?
  - a. PROBE Should this distribution be altered in any way?
  - b. PROBE If so, how are programmatic goals neglected by the current distribution of effort across post-award activities?
  - c. PROBE What should be different?
4. How might the portfolio of post-award activities need to be altered as the program progresses?
  - a. PROBE What post-award activities, if any, should the NIPT add to its management and oversight portfolio?
  - b. PROBE What existing post-award activities, if any, should the NIPT remove from its management and oversight portfolio?
  - c. PROBE What is the rationale for the changes?

## **Appendix C: Study questions**

This section includes the original study questions used to frame examination of the study. It is important to note that these questions do not constitute the interview questions.

### **Annual awardee meeting management and operations**

#### Describing annual awardee meeting management and operations

1. What are the goals of the annual meetings?
2. When and where have the meetings been held? How long have the meetings lasted?
3. Who participates in the annual meetings?
4. How have the meetings been structured?
5. Who chairs the meeting?
6. For each meeting activity addressed by question 4, what are the discrete roles fulfilled by participating:
7. Are there plans for future changes regarding the annual meeting?

#### Assessing annual awardee meeting management and operations

1. Were the goals of each of the annual awardee meetings achieved?
2. Are the goals of the meeting appropriate?
3. Are the activities of the meeting appropriate?
4. Do the goals and activities match?
5. Is the allocation of roles appropriate?
6. Should the NIPT, ECG, and NDC teams meet more than once a year?
7. What is the perceived value of the meeting by the NIPT, ECG, NDCs, other participants?

### **Site visits**

#### Describing the site visits

1. Who visits the NDCs?

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2. When do site visits occur and how long do they last?
3. What are the goals of the site visits?
4. How are the site visits structured?
5. Who chairs the site visit?
6. For each site visit activity addressed by question 4, what are the discrete roles fulfilled by participating:
7. What occurs after each site visit?
8. What regarding the goals and/or activities of the site visits has changed over time?
9. Are there plans for future changes?

Assessing the site visits

1. Should the site visits be structured differently?
2. Why have some NDCs been visited more than others?
3. Were the goals of the site visits achieved?
4. Are the goals of the site visits appropriate?
5. Are the activities of the site visits appropriate?
6. Do the goals and activities match?
7. Is the membership of the site visit teams appropriate?
8. Is the allocation of roles appropriate?
9. Is the content of the feedback provided to the host NDC by the site visit team appropriate?
10. What is the perceived value of the site visits and feedback by the NIPT, ECG, NDCs, other participants?

## **Progress report review and feedback**

### Describing progress report review and feedback

1. Who reviews the progress report?
2. What are the goals of the progress report and progress report review and feedback?
3. What is the general content of the progress report and progress report feedback?
4. What activities entail the progress report review and feedback?
5. What regarding the goals and/or activities of the progress report review and feedback has changed over time?
6. Are there plans for future changes?

### Assessing progress report review and feedback

1. Is the content of the progress reports appropriate?
2. Do the NDCs meet all of the content requirements in their respective progress reports?
3. Is the timing of the progress report review and feedback “strategic”?
4. Is all of the content of the progress reports utilized?
5. Do the progress reports provide sufficient information for making budget decisions?
6. Is the content of the feedback provided to the author NDC appropriate?
7. What is the perceived value of the progress reports and feedback by the NIPT, ECG, NDCs, other participants?

## **Allocation of set-aside funds and budget management**

### Describing the allocation of set-aside funds and budget management

1. What percentage of the total budget has been set aside for each year of the program?  
What are the absolute amounts for each year of the program?
2. For what purposes have set-aside funds been allocated?
3. For each purpose identified, to which NDCs have set-aside funds been allocated?

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4. For each purpose identified, who participates in allocating the funds?
5. For each purpose identified, what activities are entailed in deciding on allocations?
6. How are allocation decisions made?
7. Has an NDC's budget ever been scaled back?
8. What regarding the goals and/or activities of set-aside funds use and overall budget management has changed over time?
9. Are there plans for future changes?

### Assessing the allocation of set-aside funds and budget management

1. What is the rationale for the distribution of funds across the NDCs?
2. Are there other purposes to which set-aside funds could have been put to but have not been?
3. Is the process of allocating set-aside funds appropriate?

### **Portfolio-level questions**

1. Are there areas of expertise not represented by the NIPT roster that should be?
2. Are there areas of expertise not represented by the ECG roster that should be?
3. Is the distribution of program resources (e.g., money, time) across the post-award activities of the NIPT appropriate?
4. How might the portfolio of post-award activities need to be altered as the program progresses?

## Appendix D: About the authors

**Craig Boardman** is an Adjunct Research Staff Member at the Science and Technology Policy Institute (STPI). His research agenda is focused on the organization of multi-discipline and multi-sector research collaborations. His study has resulted in articles in science and technology policy journals as well as book chapters and an IBM Endowment for the Business of Government report on university-industry research centers. He has advised both the US and Canadian governments on center design and management. Boardman received his doctorate in science and technology policy and management from Georgia Tech in 2006. As of autumn 2008, Boardman holds an academic appointment in science and technology policy and management at the John Glenn School of Public Affairs at The Ohio State University.

**Jesse Karmazin** joined STPI as a research assistant in 2007 following his graduation from Princeton University with a Bachelor's Degree in molecular biology. He has worked on a variety of tasks for the National Institutes of Health and the Office of Science and Technology Policy. His research interests include translational biomedical research and globalization.

**Judith A. Hautala** is a Core Research Staff Member at the STPI in charge of Life Sciences. Prior to joining STPI in 2005, Dr. Hautala was Vice President, Research and Development, American Red Cross Biomedical Services and Director of the Jerome H. Holland Laboratory for the Biomedical Sciences. At the Red Cross she directed a research and development program in support of blood services and a grant funded discovery research program in areas related to transfusion medicine and novel cellular therapies. Prior to assuming the position of Vice President in January, 2002, Dr. Hautala was Senior Director, Administration for the Holland Laboratory with responsibility for intellectual property matters, negotiation of license and sponsored research agreements, and administrative services including facilities, financial management, regulatory compliance, R&D communications and core laboratory services.

Prior to joining the Red Cross in 1995, Dr. Hautala was Vice President, Business Development and then Vice President, Corporate Communications and Planning for Univax Biologics from 1993 to 1995 and Vice President, Corporate Development at Alpha-1 Biomedicals during 1992. From 1980 to 1992 she was with Genex Corporation, advancing from a Principal Research Scientist to Director of Technology Assessment to Vice President of Technology Development. In these positions, Dr. Hautala's responsibilities included strategic and business planning, R&D management, technology assessment and licensing, business development, intellectual property management and investor and public relations.

Dr. Hautala received a B.A. in chemistry from Colorado College in 1967 and a Ph.D. in organic chemistry from Northwestern University in 1970. She conducted postdoctoral research in biochemistry at Memorial Sloan Kettering Cancer Center and held a research and teaching molecular biology appointment in the Interdepartmental Genetics Program at the University of Georgia.