Process Evaluation of the National Institutes of Health Director's New Innovator Award Program: FY 2007–2009

FINAL REPORT

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Executive Summary

The National Institutes of Health (NIH) Director's New Innovator Award (NIA) was initiated in fiscal year (FY) 2007. According to program leadership, the NIA was the first program at the NIH that aimed to support both highly innovative research and early-career investigators. Given these novel features, a process evaluation of the NIA was deemed necessary for assessing whether the program design and implementation and participation were consistent with program goals. The NIH Office of the Director asked the IDA Science and Technology Policy Institute (STPI) to conduct a process evaluation of the NIA program to inform future years of program planning.

This report documents STPI's evaluation of the first three years of the NIA program. It addresses the evolution of program design and implementation and program participation. An analysis of the characteristics of the NIA participants and application scores are included. Additionally, the report describes applicants' and participating reviewers' perceptions of the program and provides findings and recommendations.

Program Design and Implementation

The NIA program was modeled largely after the NIH Director's Pioneer Award. Both programs had review criteria that emphasized the creativity of the investigator in addition to the merits and potential impact of the proposed project. The applications for both programs were relatively brief, and the review processes were conducted independently, instead of through traditional study sections. To be eligible for the NIA, applicants were required to be "early-stage investigators,"[1] and applicants could not have been the principal investigator on an R01 or equivalent NIH grant before applying for the NIA. Awards were for $300,000 per year for five years. Between FY 2007 and 2009, 115 New Innovator Awards were granted, totaling $172.5 million in direct costs.

The program design remained largely unchanged across FY 2007–2009, except in FY 2009 when an additional review phase was added. In all three years of the NIA program, each application was reviewed and scored independently by three external reviewers. NIA program leadership then ranked the applications by averaging the Overall Scores, and the highest scored applications were considered finalists. In FY 2007–2008, finalist applications were sent in order of their ranking as a recommendation for funding to the NIH Director, who made the final selection of awardees. In FY 2009, the finalist applications were scored by a second set of reviewers, and were ranked once more by program leadership using the second set of scores. The final ranking was sent to the NIH Director as a recommendation for funding. No other substantial changes occurred to the program process in the first three years.

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[1] Applicants were required to have received their most recent doctoral degree or completed their medical residency no earlier than 10 years before the release of the request for applications to be eligible.

Program Participation

Applicants and Awardees

Over the first three years of the program, 2,786 individuals applied for the NIA. Of those individuals, 286 applied in two or more years, for a total of 3,142 applications. In general, repeat applicants did not have higher odds of receiving an award (except for FY 2008, where finalists who were re-applicants to the NIA had increased odds of being awarded). The percentage of women who applied to the program ranged from 26% to 36% across FY 2007–2009, and women comprised 37% of all awardees. The gender distribution of the finalists or awardees was not significantly different from that of the total applicant pool.

Of the applicants who responded to the survey, 56% were White, 27% were Asian; 3% were Black or African American; less than 1% were American Indian, Alaska Native, Native Hawaiian, or other Pacific Islander; and 13% did not disclose their race. Overall, 81% of the applicants who responded to the survey identified as Not Hispanic or Latino; 5%, as Hispanic or Latino; and 15% did not disclose their ethnicity. There was no statistically significant difference between the distribution of the race or ethnicity of the finalists and awardees and that of the total applicant pool, based on survey data.

A majority of NIA applicants held PhDs (64%) and 9% and 10% held MDs and MD/PhDs, respectively. The degree distribution of awardees was significantly different from that of the total applicant pool, as fewer MDs were awarded than expected based on the total applicant pool. The average amount of time since receiving a terminal degree was 7.4 years for all applicants, and the median was 7 years. The average number of years since receiving a terminal degree was not significantly different for awardees or finalists, compared to applicants. At the time of applying to the NIA, 75% of applicants had not previously received NIH funding; of the 25% who had received NIH funding, the R21, "K" awards, and "F" fellowships were the most common form of support received.

Applicants were required as part of the application process to classify their research into one of ten research area categories. In the first three years, the Molecular and Cellular Biology and Clinical and Translational Medicine were the most common research areas, representing 20% and 22% of all proposed projects, respectively. Awardees were clustered in a small number of institutions; Stanford University, University of California San Diego, Massachusetts General Hospital, University of California Los Angeles, University of Minnesota Twin Cities, Johns Hopkins University, Massachusetts Institute of Technology, Yale University, and Princeton University represented over 40% of awardees and 14% of the total applicant pool.

External Reviewers

A total of 321 individuals participated in at least one year of NIA review, and 45 participated in multiple years for a total of 373 participation counts. In FY 2007, due to the rapid commencement of the program, external reviewers were recruited in a shorter period of time than in later years. Thus, individuals who had previously reviewed for the NIH Director's Pioneer Award were targeted for recruitment due to the

similarities of the review processes; consequently, more than a third of NIA reviewers that year had also reviewed for the NIH Director's Pioneer Award.

NIA program leadership sought reviewers who were well-accomplished senior investigators, and specifically recruited individuals who were known to be mentors to junior investigators. Overall, across the first three years of the NIA, external reviewers were predominately senior investigators, as 73% had obtained a terminal doctoral degree more than 20 years before reviewing. Approximately two-thirds of reviewers were male (66%) and one-third were female (34%). Reviewers predominately held PhDs as terminal degrees (67% held PhDs; 21%, MDs; 10% MDs/PhDs; and 3%, other doctorate degrees). As part of the review process, the three reviewers who evaluated each application were matched to the subject area of the proposal; thus, the research area distribution of reviewers matched that of the applicant pool.

Perceptions Regarding the NIA

Applicants

To gain insights into applicants' perceptions regarding the application process, STPI conducted a web-based survey of all NIA applicants who submitted proposals to the program between FY 2007–2009. Based on survey responses, more than half of applicants (58%) thought the request for applications was clear in describing the kind of investigator or idea the program sought to fund. Surveyed applicants were mostly attracted to the NIA because it supports creative new investigators and funds nontraditional ideas. Some applicants also indicated interest in receiving targeted feedback on how to improve their research proposals for future submission.

Applicants suggested the research area categories were too broad, which prevented reviewers from being accurately matched to the scientific area of the proposals. Over 80% of applicants reported collecting preliminary data before submitting an application, and those who did not collect data were concerned that not including data negatively affected how their applications were reviewed.

More than half (53%) of surveyed applicants thought it was at least "somewhat likely" their proposals could have been supported with other funding mechanisms, and 58% indicated their NIA proposals did not represent a significant departure from their previous research. This finding demonstrates the breadth of the program design; at least half of the surveyed applicants proposed ideas that were not substantially different from their previous work and were likely to have received traditional funding, such as the NIH'S R01 grant mechanism. However, 86 survey respondents also applied for an R01 in the same year they applied to the NIA, and 76 of these applicants reported submitting riskier elements of the idea, or a completely different idea from the one proposed for the R01. This finding indicates that applicants recognized the purpose of the NIA is to serve as a complement to traditional funding mechanisms.

Reviewers

STPI conducted interviews based on a purposive sample of external reviewers to gather information regarding the reviewers' perceptions of the NIA program, and their participation in the review process. Reviewers may have understood the review criteria and the program goals, but they had difficulty

interpreting the innovativeness criterion because the definition of "innovation" was not made clear. Nonetheless, reviewers frequently reported using the innovativeness criterion most critically when assigning an Overall Score to an application. Only about 10% of the reviewers stated that the proposals were neither innovative nor outside the realm of convention. When an additional phase of review was added in FY 2009, the specific purpose each phase intended to serve in the selection process was not clear to reviewers.

Reviewers reported assigning the Top 4 in a variety of ways; some relied on tangible criteria such as a principal investigator's potential, degree of innovation, feasibility, potential impact, and highest scoring applications; others relied on intuition. Reviewers indicated that the Top 4 designation may not be the most efficient method of identifying the strongest applications, as often fewer or more than four applications deserved the distinction. Preliminary data had a positive effect on most interviewed reviewers (69%); thus, they suggested the supplement should either be required or not accepted. A third of the reviewers interviewed for this evaluation were not comfortable evaluating applications outside their area of scientific expertise. This often led to missing scores, as reviewers chose not to review applications when they felt they could not accurately evaluate the subject area.

Although reviewers were mostly comfortable reviewing independently, they would have liked feedback on how their scores compared to those of other reviewers. A majority of the interviewed reviewers (82%) thought that the NIA is adding value to the NIH, but believed it may be too early to assess the effects of the program. Most reviewers enjoyed the review process, and said they would participate again in the future.

Applications and Scoring Analyses

Reviewers were instructed to score applications by the three review criteria (the scientific problem, innovativeness, and the qualification of the investigator) and to assign an Overall Score. Across the first three years of the NIA, the criterion scores positively correlated with the Overall Scores, and the Innovativeness criterion had the strongest correlation. The Overall Scores and Average Overall Scores for applicants were unimodal and symmetric in all three years, and applicants who were selected as finalists typically received the highest scores in the distribution. In FY 2009, when finalists from Phase I were scored by a second set of reviewers in Phase II, their Overall Scores were redistributed to be unimodal and symmetric. This indicates that reviewers assigned scores comparatively, and within the pool of applications they were reviewing.

Men received significantly higher scores and more Top 4 votes per applicant than women in FY 2007, although in other years the differences between scores and number of Top 4 votes by gender were not significant. Applications in behavioral and social sciences received significantly lower scores in FY 2007, but there were no significant differences in scores across research areas in other years.

The level of agreement between external reviewers' scores was higher in finalists and in awardees than for the total applicant pool, but overall agreement decreased over time from FY 2007 through 2009. Agreement among reviewers within each research area varied from fair to good, and agreement for all reviewers ranged from fair to moderate when assigning each of the criterion scores and the Overall Score.

In all three years, applicants with the highest Average Overall Scores and the most Top 4 votes had the highest likelihood of advancing as finalists. Although the tiered ranking was primarily based on the Average Overall Scores and Top 4 votes, the final selection of awardees was not solely based on scores, as discretion was used by NIA program leadership and by the NIH Director to select awardees based on priorities across the NIH or specific to its institutes and centers.

Findings and Recommendations

Program Design and Implementation

On the whole, the NIA program has been implemented without significant problems. The goals of the program are broad and can include a range of objectives. Because of this broadness, while program participants found the goals of the program to be clear, they had additional expectations around support on career development. Certain aspects of the program's activities were viewed by awardees as either being very useful for new investigators (e.g., allocation of all funds up front), or lacking in some way (e.g., no provision of mentoring or career development support).

Scoring analysis revealed that applicants with the highest average scores received awards. Using reviewer agreement as a selection tool precludes applications that reviewers disagreed on, which may include some innovative applications. The program may wish to consider further analysis of applications that have reviewer disagreement.

NIA allowed applicants to submit preliminary data, but did not require preliminary data. Although some reviewers stated that preliminary data in an application affected their review, and most applicants submitted preliminary data, STPI found no evidence that collecting preliminary data increased the odds of applicants advancing in the selection process. The NIA program should consider the purpose of preliminary data and decide whether changes to the review process are necessary.

The program evolved in its first three years without significant changes to the design or implementation. A two-phase review process instituted in FY 2009 caused some confusion to reviewers, who were unclear as to the purpose of each phase. The NIH should provide better guidance to reviewers on the purpose of each phase.

Program Participation

Data show that approximately three-quarters of NIA applicants and awardees did not have previous NIH funding. Of those who did, "K" and "F" awards were the predominant sources. The demographic distribution of awardees with respect to gender, seniority, race/ethnicity, and subject area distribution reflected that of the applicant pool.

Generally, reviewers were pleased with their participation in the program. However, many stated that they would have liked to have more engagement from the NIA program, including getting feedback on whether their scores were useful and being informed about who was awarded the NIA.

Contents

List of Exhibits

1. Introduction

This chapter provides an overview of the National Institutes of Health (NIH) Director's New Innovator Award (NIA) program and describes the purpose and the design of the process evaluation.

1.1 Overview of New Innovator Award Program

The NIA program was initiated in FY 2007 as part of the High-Risk Research Initiative of the NIH Roadmap for Medical Research.[1] The program design was largely based on that of the NIH Director's Pioneer Award (NDPA), the flagship program of the Roadmap Initiative that was created as a new mechanism of funding biomedical research intended to complement the more traditional NIH grants. Like the NDPA, the NIA seeks to fund exceptionally creative investigators who have extraordinarily innovative ideas but no preliminary data, something typically required to fare well in more traditional review processes.[2] However, the NIA differs from the NDPA in that it also seeks to support promising new investigators who are no more than 10 years out from their graduate degrees. This aspect of the program also made the NIA a complement to other initiatives within the NIH to support new investigators, such as the NIH Pathway to Independence Program, started in 2006 to facilitate the transition from a postdoctoral position to becoming an independent researcher.[3]

Given this difference in program design, the NIH created the DP2 activity code for the NIA.[4] The features of the DP2 mechanism include a relatively short application, review criteria focused on the innovative potential of the research, and independent proposal review by external reviewers who do not meet in study sections. The NIA provides awardees $300,000 in direct costs each year for five years—an award both larger in size and longer in duration than traditional single investigator awards at the NIH.[5] In response to the NIA program announcements for FY 2007–2009, 2,786 individuals applied to the program, some applying in multiple years, for a total of 3,142 candidacies. Three groups of awards have been made for a total of 115 awardees in a broad range of scientific disciplines. A list of the FY 2007–2009 awardees and titles of their NIA-funded projects are given in Appendix A.

1.2 Overview of Process Evaluation

The NIA, like other programs under the Roadmap Initiative, represents a new mechanism of funding for the NIH. According to program leadership, the NIA is the first program at the NIH that aims to support

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[1] The Roadmap was institutionalized by Congress in the NIH Reform Act of 2006 as the Common Fund, a central pool of money designed to address issues of interest to all twenty-seven of the NIH's institutes and centers (ICs). See http://commonfund.nih.gov/about.asp.

[2] The NIH Director's New Innovator Award Program press release. March 9, 2007, available at http://www.nih.gov/news/pr/mar2007/od-09.htm.

[3] The Pathway to Independence Award, available at http://grants.nih.gov/grants/new_investigators/index.htm#indaward.

[4] An activity code is used to define or categorize research-related programs supported by NIH. A list of activity codes for NIH extramural grants is available at http://grants.nih.gov/grants/funding/ac_search_results.htm.

[5] Due to the uncertainty of the continued funding for the program, NIH chose to disburse all funds up front, instead of on an annual basis.

both highly innovative research and early-career investigators. Given these novel features, a process evaluation of the NIA was deemed necessary for assessing whether the program design, implementation, and participation were consistent with program goals. The NIH Office of the Director commissioned the IDA Science and Technology Policy Institute (STPI) to conduct a process evaluation of the first three years (FY 2007–FY 2009) of the NIA, to inform future years of program planning.

STPI has conducted several program evaluations of funding opportunities supporting high-risk, high-reward research in the federal research and development (R&D) system, and recently completed a process evaluation of the first five years of the NDPA program.[6] The process evaluation of the NIA was largely informed by the NDPA process evaluation, both to allow for comparisons where appropriate, as well as in response to stakeholder feedback that such an evaluation structure was useful for program purposes. The study questions guiding this evaluation focused on program design, implementation, and participication. Data sources included both individuals directly involved in the program, such as applicants, reviewers, and program leadership and staff, as well as the Evaluation Advisory Committee composed of senior NIH scientists and evaluation officials with programmatic knowledge of NIH activities. The process evaluation was conducted over the period of fall 2008 to fall 2010.

This report presents the findings from the evaluation of the first three years of the NIA. It is divided into eight chapters:

- Chapter 1 (this chapter) introduces the program and provides an overview of the evaluation.
- Chapter 2 summarizes the evaluation methodology.
- Chapter 3 describes the NIA program design and implementation.
- Chapter 4 describes the characteristics of the applicants and the external reviewers.
- Chapter 5 outlines the awardees' perceptions of the program.
- Chapter 6 summarizes the reviewers' perceptions of the selection process.
- Chapter 7 offers analyses of scoring trends across the proposals.
- Chapter 8 summarizes the overall assessment of the program and provides recommendations for future years of program implementation.

Appendixes include supplementary data not included in the main chapters. Appendix A presents a list of the awardees and their proposed research projects from the first three years of the program. Appendix B provides the sources of data used to answer the study questions. Appendix C describes statistical tests used throughout the report. Appendix D presents the applicant survey, and Appendix E contains the reviewer interview protocol. Appendixes F and G contain additional survey and interview questions that informed this evaluation, but did not warrant interpretation in the main report.

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[6] Bhavya Lal, Ritu Chaturvedi, Adrienne Zhu, Mary Beth Hughes, Stephanie Shipp, Christina Kang, Amy Marshall, and Elmer Yglesias. Process Evaluation of the National Institutes of Health Director's Pioneer Award Program: FY 2004–2008, IDA Document D-4014, January 2010, available at http://nihroadmap.nih.gov/pdf/PioneerAwardProcessEvaluation_2004-2008.pdf and at https://www.ida.org/upload/stpi/pdfs/idadocumentd-4014final.pdf.

2. Evaluation Methodology

This chapter describes the design of the process evaluation and discusses data sources, analyses, and study limitations.

2.1 Process Evaluation Design

This process evaluation was designed to study the implementation of the NIA with regards to program goals, and to provide recommendations for how program activities could be improved. The process evaluation was designed around three main domains of inquiry: (1) assessing whether the NIA was designed and implemented according to its goals; (2) assessing the characteristics of the participants of the NIA; and (3) addressing program evolution, particularly changes to the selection process.

The high-level study questions[8] and findings were organized into three categories: Program Design and Implementation, Program Participation, and Program Evolution. These categories are illustrated in Exhibit 1 and described as follows:

- Program Design and Implementation

    – *Genesis and Structure*: What was the origin of the NIA program? What was the structure of the program and how did it differ from *other* programs at the NIH?

    – *Outreach:* How was the program designed and implemented to reach new investigators?

    – *Selection Process and Criteria*: How was the selection process designed? How were the selection criteria chosen and *implemented*?

- Program Participation

    – *Applicants*: What were the demographic and scientific characteristics of the applicants? Wh*at were the applicants' perceptions of the NIA program and processes?*

    – *Reviewers: What were the demographic and scientific characteristics of the reviewers? What were the reviewers' perceptions of the NIA program and processes?*

    – *Applications: What were the characteristics of the applications? How were awards chosen? What about the submitted proposals (and especially those selected for awards) showed inno*vativeness?

- Program Evolution

    – *Design, Implementation, and Participation Changes*: How did the program's design, *implementation*, and participation evolve over the first three years?

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[8] See Appendix B for the detailed study questions.

To assist and advise in the study design process, the Office of the Director and the Office of Behavioral and Social Sciences Research convened a five-member NIA Evaluation Advisory Committee to guide the study and its methodology.[9]

Exhibit 1. Process Evaluation Areas of Inquiry

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Program Design and
Implementation  ──►  Genesis and Structure  ─┐
                ──►  Outreach               ─┤
                ──►  Selection Process and   │
                     Criteria               ─┤
                                             │
Program Participation ──► Applicants        ─┤──►  Study Questions
                      ──► Reviewers         ─┤
                      ──► Applications       │
                                             │
Program Evolution  ──►  Design,             ─┘
                        Implementation, and
                        Participation Changes
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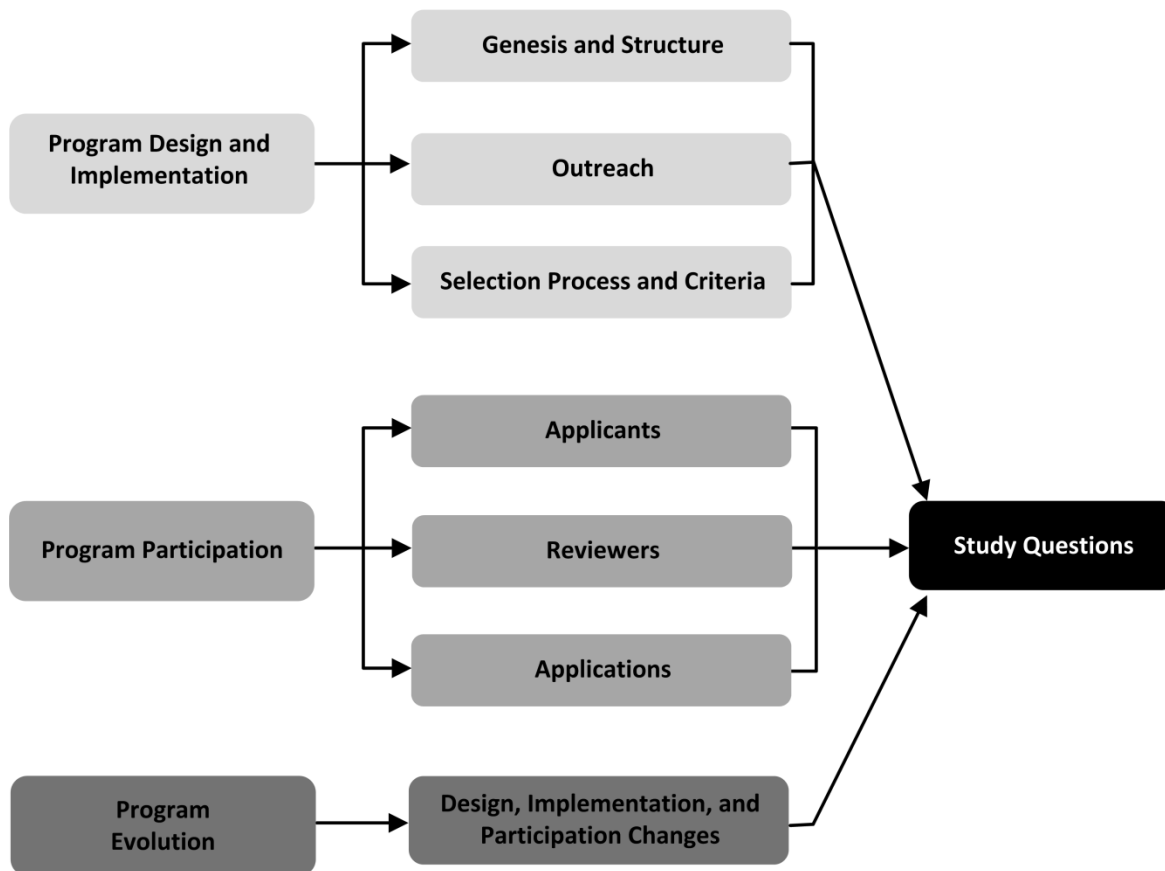
2.2   Data Collection, Analyses, and Limitations

The data for the process evaluation were collected from five main sources: (1) interviews with, and information (including application scores and reviewer comments) provided by, NIA program leadership[10] and staff;[11] (2) NIH Information for Management, Planning, Analysis, and Coordination

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[9]   Members are *Juliana Blome,* Chief of the Office of Program Analysis and Evaluation, National Institute of General Medical Sciences; *Judith Greenberg*, Director of the Division of Genetics and Developmental Biology, National Institute of General Medical Sciences; *Teri Levitin*, Director of the Office of Extramural Affairs, National Institute on Drug Abuse; *James Onken*, Special Assistant to the Deputy Director, Office of Extramural Research; and *Betsy Wilder*, Deputy Director of the Office of Strategic Coordination, Division of Program Coordination, Planning and Strategic Initiatives, Office of the Director.

[10]   "NIA program leadership" refers to Jeremy Berg, Director of National Institute of General Medical Sciences, and the Scientific/Research and Peer Review Contacts for the program, which were Judith Greenberg, Director of the Division of

(IMPAC) II database of funding and application information for all its programs; (3) a survey of NIA applicants; (4) interviews with external reviewers who scored applications; and (5) focus groups held with a subset of NIA awardees from FY 2007 to FY 2009. See Appendix B for the study questions (both high level and detailed questions).

2.2.1 Program Design and Implementation

To obtain information regarding the genesis of the NIA, the program design, the selection process, and their evolution, STPI conducted several interviews with NIA program leadership. Additional information regarding program history and design were obtained from the official request for applications (RFA) and program announcement (PA) listed on the NIA website.[12] STPI also conducted interviews with NIH staff focused on communications to gather insight into program outreach.[13]

2.2.2 Program Participation

2.2.2.1 Applicants and Awardees

Demographic data and other information on the NIA applicants were obtained through the NIH IMPAC II database. To gain insights into applicants' perceptions regarding the application process, STPI conducted a web-based survey of all NIA applicants who submitted proposals to the program between FY 2007–2009. The response rates for the survey, conduced between February and April 2010, are listed in Exhibit 2. The response rates for all individuals who submitted a proposal was 64.7%. The response rate is slightly higher (66.4%) when those who were unreachable are not included.

The Survey of Applicants for all three years was launched simultaneously; applicants who had applied in more than one year were asked to answer questions with regard to their most recent application. Thus, the number of surveys sent out for each year does not correspond to the number of applicants in a given year. Also, the interval between the time of applying to the NIA and receiving the survey appeared to affect the response rate for each year, which ranged from 60.5% for FY 2007 applicants, who received the survey three years after applying, to 78.5% for FY 2009 applicants, who received the survey less than a year after applying to the program. Of the 71 individuals who could not be contacted, 69 had untraceable email addresses and two were deceased.

Genetics and Developmental Biology, National Institute of General Medical Sciences, in FY 2007–2008, and Richard Okita, Program Director of the Pharmacological and Physiological Sciences Branch, National Institute of General Medical Sciences, in FY 2009.

[11] "NIA program staff" refers to individuals involved with the administrative processes for the program across the first three years, which includes Shan McCollough and Margaret Schnoor, Program Analysts for the Office of the Director, National Institute of General Medical Sciences.

[12] See http://commonfund.nih.gov/newinnovator/.

[13] Interviews were conducted with two NIH Communications personnel: Ann Dieffenbach, Communications Director of National Institute of General Medicine Sciences on January 8, 2010; and Karen Silver, Communications Director, Division of Program Coordination, Planning, and Strategic Initiatives on January 19, 2010.

Exhibit 2. Survey of Applicants Response Rates by Year, FY 2007–2009

FY	Surveys Completed	Individuals Contacted	Response Rate (% of Total Individuals)	Response Rate of Applicants*	Response Rate of Finalists*	Response Rate of Awardees*	Unreachable Individuals	Response Rate (% of Possible Responses)
2007	1,136	1,879	60.5%	51.8%	50.0%	86.7%	59	62.5%
2008	345	497	69.4%	56.2%	40.4%	93.5%	10	70.8%
2009	321	409	78.5%	73.1%	75.6%	92.6%	2	78.9%
Total	1,803	2,786	64.7%*	N/A	N/A	N/A	71	66.4%

*Total response rate by application stage (Applicant, Finalist, Awardee) could not be calculated because survey respondents were counted only for their most recent application. Also, 36 survey respondents (11 in FY 2007, 16 in FY 2008, and 9 in FY 2009) had a technical malfunction during submission; thus, although their survey responses were intact, they could not be linked to their application stage. These individuals were not counted in the calculation for response rate by application phase, but are counted as a survey completion.

In addition to the survey, STPI held two focus groups with NIA awardees during the 2009 and 2010 annual NDPA Symposia, to inform the evaluation on awardees' perspectives. Each focus group included nine awardees. Topics discussed during the focus group included: differences between the NIA and other NIH grants; perceptions of the NIA program; insight into outcomes possible under NIA; and recommendations for program improvement.

2.2.2.2 External Reviewers and the Review Process

Information regarding reviewer recruitment and training was obtained from interviews with, and information provided by NIA program staff. Reviewers' degrees and seniority information were collected from curricula vitae and personal websites. STPI conducted interviews based on a purposive sample of external reviewers[14] to gather information regarding the reviewers' perceptions of the NIA program, and their participation in the review process. Exhibit 3 lists the number of external reviewers interviewed from each year. Given that the second review phase (DP2) was a new stage introduced in FY 2009, a larger percentage of reviewers from that phase were sought for interviews.

Exhibit 3. NIA External Reviewers Interviewed by Year, FY 2007–2009

Year	Number of Reviewers	Number of Interviews	Percentage of Total
2007	197	45	23%
2008	92	22	24%
X02 2009	68	24	37%
DP2 2009	16	10	63%

2.2.2.3 Applications and Scoring Analyses

NIA program staff provided application scores, applicant research areas, and reviewer comments. Comparisons made across scores and a range of applicant characteristics were tested for statistical significance where appropriate. The various statistical tests used for each comparison are identified in footnotes, and a brief description of the tests and underlying rationales for their usage are presented in Appendix C.

2.2.3 Program Evolution

Information on the evolution of the NIA program was also collected from data sources noted previously. Throughout the report, program evolution is addressed when the aspect under question changed over the first three years of the NIA.

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[14] Interview requests were sent to a broad spectrum of reviewers so that the total pool of reviewers interviewed would be diverse in terms of demographics and scientific background. If a reviewer declined to be interviewed, another reviewer with similar characteristics was contacted to maintain the diversity.

3.   Program Design and Implementation

This chapter outlines the conception and design of the NIA and summarizes the communications outreach to attract applicants to the program. The application selection process is described and changes made to the program and its processes between FY 2007 and FY 2009 are summarized. The analyses herein are based on the NIA program website, requests for applications (RFAs), and interviews with NIA staff and Communications Directors.

3.1   Origin of the NIA Program

In the years leading up to the start of the NIA, several significant events occurred at the NIH to promote highly innovative, biomedical research. Shortly after becoming NIH Director, Elias A. Zerhouni established the Roadmap Initiative, an interagency effort to address in gaps in biomedical research. The Roadmap was designed to support research opportunities that did not fall under a single NIH institute or center, but needed to be addressed for the advancement of biomedical science.[15] As part of the Roadmap Initiative focused on new organizational models for funding science, a "high-risk research" theme was developed. The NDPA program became the flagship program of the High-Risk Research Initiative established in 2004.

In April 2006, two years after launching the NDPA, Zerhouni presented his budget request statement to Congress, where he proposed to increase the Roadmap Initiative, then described as "an incubator for new ideas and initiatives that will accelerate the pace of discovery,"[16] by $113 million. Furthermore, the NIH Reform Act of 2006, under discussion in the fall of 2006 and signed into law January 15, 2007, specifically authorized the NIH Director to award grants for bridging biological sciences with formerly disparate disciplines such as physical, chemical, mathematical, and computational science, and to establish programs specifically promoting high-impact, cutting-edge research.[17] To fulfill the new responsibilities of NIH and to show commitment to supporting high-risk research programs, Zerhouni conceptualized a new program, known as the New Innovator Award, which would be an extension of the NDPA, but focused on new investigators.[18]

3.2   Planning Process

In February 2007, Zerhouni asked several NIH staff, who at the time were participating as NDPA program leadership, to design a program that could be launched within the fiscal year; thus, the first year of the NIA was implemented under tight deadlines. As a result, NIH did not use a working group (as was done for the NDPA program) or other strategic planning (handled by the Office of Portfolio Analysis and

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[15] See http://nihroadmap.nih.gov/overview.asp.

[16] FY 2007 Director's Budget Request Statement to Congress, Dr. Elias A. Zerhouni, Director, April 6, 2006, http://www.nih.gov/about/director/budgetrequest/fy2007directorsbudgetrequest.htm.

[17] See http://www.nih.gov/about/reauthorization/.

[18] Interviews with NIA program staff, October 2008.

Strategic Initiatives for the Roadmap Initiative programs). The FY 2007 process was compressed over a six-month period, as opposed to the usual twelve-month process used in subsequent years of the program (Exhibit 4).

Exhibit 4: NIA Activities Timeline, FY 2007–2008
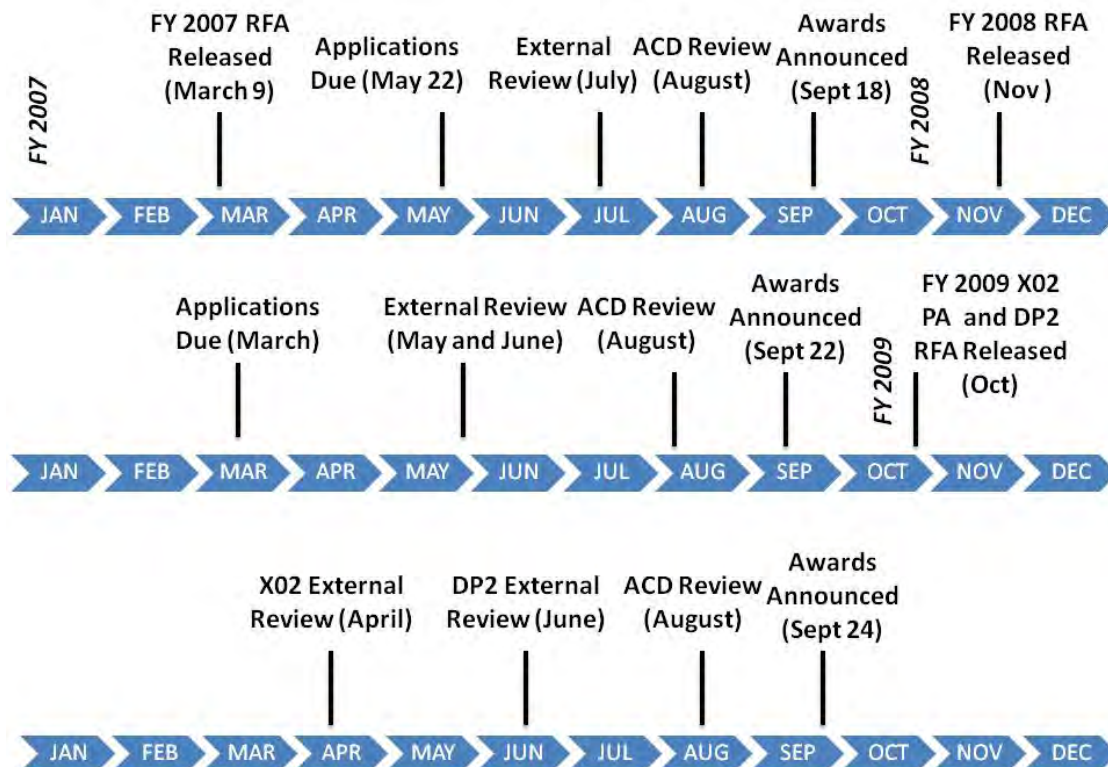
Around the time of the program design, the NIH was exploring novel ways to support not only high-risk research, but also new investigators. In 2005, recognizing that number and percentage of grants awarded to young investigators was dropping, the NIH requested the National Academies of Sciences to "recommend mechanisms to foster the independence of new investigators in biomedical research."[19] Among other recommendations, the panel suggested the NIH establish a program that supported new investigators through a research project grant similar to an R01, but with a longer time frame and using "previous experience" as a substitute for the typical preliminary data required in the R01 selection process. It is unclear how much of a role the recommendation played in the planning of the NIA, but supporting new investigators was a goal from the origin of the program.

NIH released a Notice of Intent to Publish a Request for Applications on February 21, 2007, stating that the program would "extend the concept of the NIH Director's Pioneer Awards to support new

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[19] National Academies Press, "Bridges to Independence: Fostering the Independence of New Investigators in Biomedical Research," http://www.nap.edu/catalog.php?record_id=11249. This report appears to have guided the formation of the K99/R00 "Pathways to Independence" program launched in 2006.

investigators of exceptional creativity who propose innovative approaches that have the potential to produce an unusually high impact on significant problems in biomedical and behavioral research."[20]

The notice specified that application eligibility would be limited to new investigators: researchers who had not yet received an R01 grant and who were within 10 years of receiving their terminal degree. The application would be briefer than the application for an R01, preliminary data were not required but would be accepted, and letters of recommendation were not required and would not be accepted. Other aspects of the program were left undefined at that time. Two weeks later, on March 9, 2007, the RFA (RFA-RM-07-009) for the "NIH Director's New Innovator Award Program" was released.[21]

3.3   Program Goals and Objectives

The purpose of the NIA program, as defined in the FY 2007 RFA, was as follows:

> The NIH Director's New Innovator Award, created this year, addresses two important goals: stimulating highly innovative research and supporting promising new investigators. New investigators may have exceptionally innovative research ideas, but not the required preliminary data to fare well in the traditional peer review system. As part of its commitment to increasing the success of new investigators, NIH has created the NIH Director's New Innovator Award to support exceptionally creative new investigators who propose highly innovative approaches that have the potential to produce an unusually high impact.[22]

The statement as written implied that NIH had two goals for the program: funding innovative research and supporting new investigators. In subsequent years, the program purpose stated in the RFA was changed to read:

> To support a small number of new investigators of exceptional creativity who propose bold and highly innovative new research approaches that have the potential to produce a major impact on broad, important problems in biomedical and behavioral research.

Program leadership stated that the semantic change did not signify a change in program goals.[23] Although not explicitly stated in the RFA, program leadership stated the program has a third goal of changing the culture at the NIH to encourage more programs that support high-risk, high-reward research and new investigators.[24] In launching the program, Zerhouni stated he considered new investigators the "future of science" and innovative research as its "lifeblood."[25]

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[20] Notice of Intent to Publish a Request for Applications for the NIH Director's New Innovator Awards, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-047.html.

[21] See http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-07-009.html.

[22] See http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-07-009.html.

[23] Interviews with NIA program leadership, October 2010.

[24] Interviews with NIA program staff, October 2010.

[25] Press Release: NIH Director Launches Program for Innovative New Investigators, http://www.nih.gov/news/pr/mar2007/od-09.htm.

3.4 Program Design

Given the goals and objectives outlined in the previous section, the NIH designed the NIA program in a way that differed from other programs at the NIH. In order to represent the NIA program with respect to inputs, activities, outputs, and outcomes, STPI created the program logic model in Exhibit 5 with input from NIA program leadership. The top boxes represent the aspects of the program that are designed to lead to advances in biomedical and behavioral research and career advancement of the awardees, and the bottom boxes represent the inputs, activities, and outputs designed to accomplish the implicit goal of changing the culture at the NIH.

We turn now to discussion of how the key elements of the program's design support the program's eligibility, activities, and process goals.

3.4.1 Eligibility

Key aspects of eligibility include:

- Applicants were required to meet the definition of "early stage investigator," which means having received their most recent doctoral degree or completed their medical internship and residency no earlier than 10 years from the release date of the RFA and no later than the receipt date for applications. Applicants could apply for a waiver of this requirement in the case of a lapse in the research period, for reasons including medical concerns, disability, family care responsibilities, extended periods of clinical training, natural disasters, or active duty military service.
- Applicants were also required to meet the definition of "new investigator," which is defined as those investigators who have never applied successfully as a Principal Investigator on an R01 or equivalent NIH grant or leader of a P01 or center grant peer-reviewed project. Grants considered "R01-equivalent" included R23, R29, R37, or U01.
- Applicants were also required to commit at least 30% of their research effort to the proposed project.[26]
- Applicants could propose projects in 10 broad research areas, representing all of biomedical and behavioral research, including those not typically represented in traditional NIH study sections (such as Instrumentation and Engineering).

Through the eligibility criteria, the NIA program has targeted investigators who have not received substantial NIH funding, are early in their careers, and who may be outside the traditional NIH grantee profile (such as physicists and engineers). These criteria correspond to the program's goal of supporting career advancement of awardees, as applicants are in their early stages and are at least suitable to have their careers advanced through such an award. Also, there may be an assumption that bringing in new researchers within the NIH fold will bring advances in biomedical and behavioral research.

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[26] In FY 2008, the required effort commitment was reduced to 25%. Program leadership stated this was mainly because many NIA awardees were also recipients of NIH "K" Awards, which required a 75% effort commitment.

Exhibit 5: Logic Model of the NIA Program

Inputs   Activities   Outputs   Outcomes

Investigator Level

PI Input — Innovative Proposal

If successful

NIA Input — Funding mechanism (amount, duration, flexibility)

- Expand research capabilities (build up group, purchase equipment, build infrastructure)
- Conduct high-risk research
  - *If successful*
- Explore other research avenues

If successful, leads to impactful and creative discoveries, which results in:

- Patents and other outputs — *Lead to*
- Publications in high-impact journals — *Lead to*
- Additional grants
- Awards — Lead to
- Increased collaboration

Advances in biomedical and behavioral research

Career progression

NIH Level

High-risk, high-reward (HRHR) Research Initiative

Not through an IC but through

Common Fund Dollars

Allows for program feature experimentation

- Award small number of researchers
- Non-traditional selection process
- Annual symposium

Greater understanding of program features for HRHR grants for young investigators

New programs to support innovative research and new investigators

Leading to

- High-impact scientific outcomes traced to NIH grants
- More applications from competitive applicants with innovative ideas
- Cultural change around funding and supporting new investigators

3.4.2 Activities

Key aspects of the program activities include:

- Awards were for $300,000 per year in direct costs, an amount similar to the annual value of R01 grants.
- Awards were for five years, a period somewhat longer than many traditional R01 grants (generally funded for 3 to 5 years), to allow investigators the freedom to undertake longer-term, more risky projects.
- All funds were disbursed in the first year of award.
- The use of funds by awardees was flexible, with no detailed budget submission required.

The activities of the program appear to be intended to directly support the pursuit of innovative research ideas leading to advances in biomedical and behavioral research. Nothing inherent in the program activities directly supports the career advancement of the awardees, such as mentoring features used by other programs to support new investigators, although some of the activities may indirectly support career advancement.

3.4.3 Process

Key aspects of the program processes include:

- The NIA program would be run centrally, out of the Office of the Director and be administered by the National Institute of General Medical Sciences. Ad hoc committees of extramural reviewers would be used for evaluating applications, as opposed to study sections in the Center for Scientific Review. Extramural review would be conducted independently with no face-to-face interaction among reviewers.
- The application was shorter than a traditional R01 application. Application materials consisted of a two-page biographical sketch of the applicant, a brief abstract, limited to 300 words or one page, describing the goals of the project, and an essay, limited to ten pages, describing the proposed research and addressing each of the three review criteria in detail:

  - The scientific problem to be addressed.
  - Innovativeness of the research proposed.
  - Investigator qualifications.

- Preliminary data were not required, but could be included.
- The review criteria were different from those of traditional NIH programs in that they emphasized the creativity of the investigator in addition to the merits and potential impact of the proposed project.

The NIA program processes appear to be largely based on the NDPA program, although there are a few differences (Exhibit 6).

Exhibit 6. Comparison of the NIH Director's Pioneer Award (NDPA) and New Innovator Award (NIA), FY 2007–2009

Criteria	NDPA	NIA	Both NDPA and NIA
Applicant Eligibility	• Open to all career stages; early and middle career particularly encouraged to apply, as long as currently engaged in research	• Most recent doctoral degree or completion of medical internship and residency must be within 10 years of the due date for applications • Must be a "new investigator" (i.e., never successfully applied for an R01 or equivalent NIH grant)	• No citizenship or residency requirements • Foreign (non-U.S.) institutions not eligible
Preliminary Data			• Not required; may be included
Review Criteria	• Importance and innovativeness of scientific problem addressed • Investigator's creativity • Suitability for NDPA mechanism (higher risk and impact, new scientific direction)	• Importance of scientific problem addressed • Innovativeness of research proposed • Investigator qualifications	• Merit of applications also assessed by: significance, approach, innovation, investigator, environment
Application Materials	• 3-5 page project proposal • 1-page maximum summary of most significant research accomplishment • 3 letters of reference	• 10-page maximum project proposal	• 300-word maximum abstract • Brief statement on how research may positively impact public health • 2-page biographical sketch • List of current and pending research support
Effort Commitment	• A minimum of 51% of research effort	• A minimum of 25% of research effort	
Budget	• Awards are for up to $500,000 per year for five years, in addition to standard Facilities and Administrative (indirect) costs	• Awards are for up to $300,000 per year for five years, in addition to standard Facilities and Administrative (indirect) costs	• No budget plan required and may not be included
Selection Process	• Independent external review phase, followed by interviews for finalists to determine finalists' rankings. • Director selects awardees	• Independent external review phase, (followed by 2nd external review phase for finalists supplemented with a teleconference to discuss applications and determine finalist rankings) • Director selects awardees	

* In FY 2007–2008, there was only one review phase.

Program staff stated that the program was created too quickly to allow for letters of reference to be collected or for an interview to be held, and that these features were not incorporated in subsequent years due to the logistic difficulties (namely, the number of awardees was greater than for NDPA).[27] Because the NIA applicants are new investigators and were thus presumed by program leadership to be less able to convey the innovativeness of their ideas than NDPA applicants, the essay proposal length was expanded to 10 pages, and all three reviewers were placed in the same area as the applicant. The lack of required preliminary data, along with the shorter application than required for traditional NIH grants, appears to be designed to support innovative research ideas that could lead to advances in biomedical and behavioral research. No requirements in the application review process directly focused on promoting the career advancement of the awardees, although the broad review criteria may have allowed for it to be interpreted by the external reviewers.

3.5   Outreach Efforts

The NIA aimed to support promising young investigators with highly innovative ideas. Given its focus on attracting a diverse applicant pool and its trans-NIH nature due to being operated out of the Common Fund, the NIH staff undertook substantial outreach efforts. Each year four different phases of communication publicized the NIA. Starting in 2008, NIH advertised the NIA and NIH Director's Pioneer Award together. The four communications phases are:

- broadcasting program launch
- linking NIH funding to scientific findings by awardees
- publicity for the NDPA Symposium[28]
- announcement of the new NIA (and NDPA) recipients

3.5.1   Overview of Outreach Structure

Prior to 2009, the National Institute of General Medical Sciences directed outreach for NIA, but starting in FY 2009, all aspects of outreach except for the symposium were transferred to the Office of the Director. Exhibit 7 describes the four phases of NIA outreach and the time during the fiscal year in which each phase occurs. Outreach begins with the program launch in the fall. Advertising for the NDPA Symposium occurs between May and September, with the actual symposium occurring at the end of September, where the new awardees for both the NDPA and NIA are announced. Scientific findings published by NDPA and NIA awardees are announced year-round on the NDPA and NIA website.[29]

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[27] Interview with NIA program staff, October 24, 2008.

[28] At the NDPA Symposium, the NIA awardees for the current year are announced, and the previous year awardees present posters of their work at a poster session.

[29] See http://commonfund.nih.gov/pioneer/AwardeeScienceNews.aspx.

Exhibit 7. Phases of Outreach for the NIA, FY 2007–2009

Phase	Description	Timeline
Program Launch	Outreach is conducted to announce the Request for Applications and the commencement of the application process.	Late Oct–Mid Nov*
NDPA Symposium	NIH publicizes the opportunity to attend the NDPA symposium or to watch it online.	May–Sep
Announcement of Awardees	NIH releases a formal announcement of awardees. This release is coordinated with the symposium, and with the awardees' institutions. [NIA awardees are announced at the symposium, and awardees from the previous year present their research at the poster session.]	Late Sep
Science Advance	Significant scientific findings by NIA recipients can be linked to NIH funding and the NIA program. The most common ways are to have an NIH official provide a quote for a journalist covering the finding or for a news release from the recipient's institution. Occasionally, NIH could elect to issue its own news release.	Year around

Source: Interviews with two NIH Communications personnel.

* The NIA was planned rapidly in FY 2007, and the first year program launch occurred closer to the start of the application period, as NIH staff announced the program in February 2007 and the RFA was released in March 2007. In subsequent years, the NIH staff begins outreach for the launch of the program between late-October and early November of the preceding fiscal year.

In the initial years of the NIA, NIH made a concerted effort to attract innovative new investigators, particularly those from underrepresented groups (minorities and women) and from research areas not traditionally funded by NIH (for example, behavioral and social scientists). With that in mind, the outreach for the NIA was conducted through multiple venues:

- Notice of Intent to Publish a Request for Applications.[30]
- Paid advertisements in prominent journals. NIH advertised the NIA program in five journals. The cost for the ads ranged from $1,084 to $7,293.
- Email announcements to professional organizations and scientific societies, such as the American Association of Medical Colleges (AAMC) and Federation of American Societies for Experimental Biology (FASEB), which sent announcements to their lists of society leaders, clinical and basic science department chairs, and research deans. NIH contracted GYMR Public Relations to conduct this outreach.[31]
- Emails to the email lists of the Roadmap Initiative and the Office of Behavioral and Social Sciences Research; the latter to better target social scientists, a discipline typically underrepresented among applicants to the NDPA program.[32]

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[30] See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-047.html.

[31] NIH contracted GYMR Public Relations to construct the email lists and lists of university departments. (http://www.gymr.com/). GYMR also identified meetings of professional organizations and scientific societies where NIH could distribute flyers for the NIA and the NDPA.

[32] In FY 2008, NIH published an article in NIH Extramural Nexus, a newsletter that provides a monthly update to the external, scientific community on the various programs of the NIH Office of Extramural Research.

- Emails to all NIH Institute communications departments with a request that they forward the program announcement to their mailing lists.
- Emails to trade publications targeting the scientific community to encourage them to cover the NIA program. Reporters from *Science*, *Nature, The Chronicle of Higher Education, The Scientist,* and *Chemical and Engineering News* were contacted and the latter two publications covered the NIA program.[33,34]

3.5.2   Program Outreach Evolution

NIA applicants surveyed as part of this process evaluation reported learning about NIA predominately through NIH email list announcements and various online sources (Exhibit 8). NIH discontinued the journal advertisements in FY 2009 due to high costs, and based on feedback that applicants were not learning about the NIA program from journal ads. Exhibit 6 affirms that journal advertisements were not a source of information about the NIA.

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[33] Bob Grant, "The NIH Calls for Risky Research," *The Scientist*, September 2009, available at http://www.the-scientist.com/blog/display/55952/.

[34] Britt Erickson, "NIH Distributes Funds for High-Risk Research," *Chemical and Engineering News*, September 2009, available at http://pubs.acs.org/cen/email/html/8739news7.html.

Exhibit 8. Applicant Survey Question: How did you hear about the NIA program?
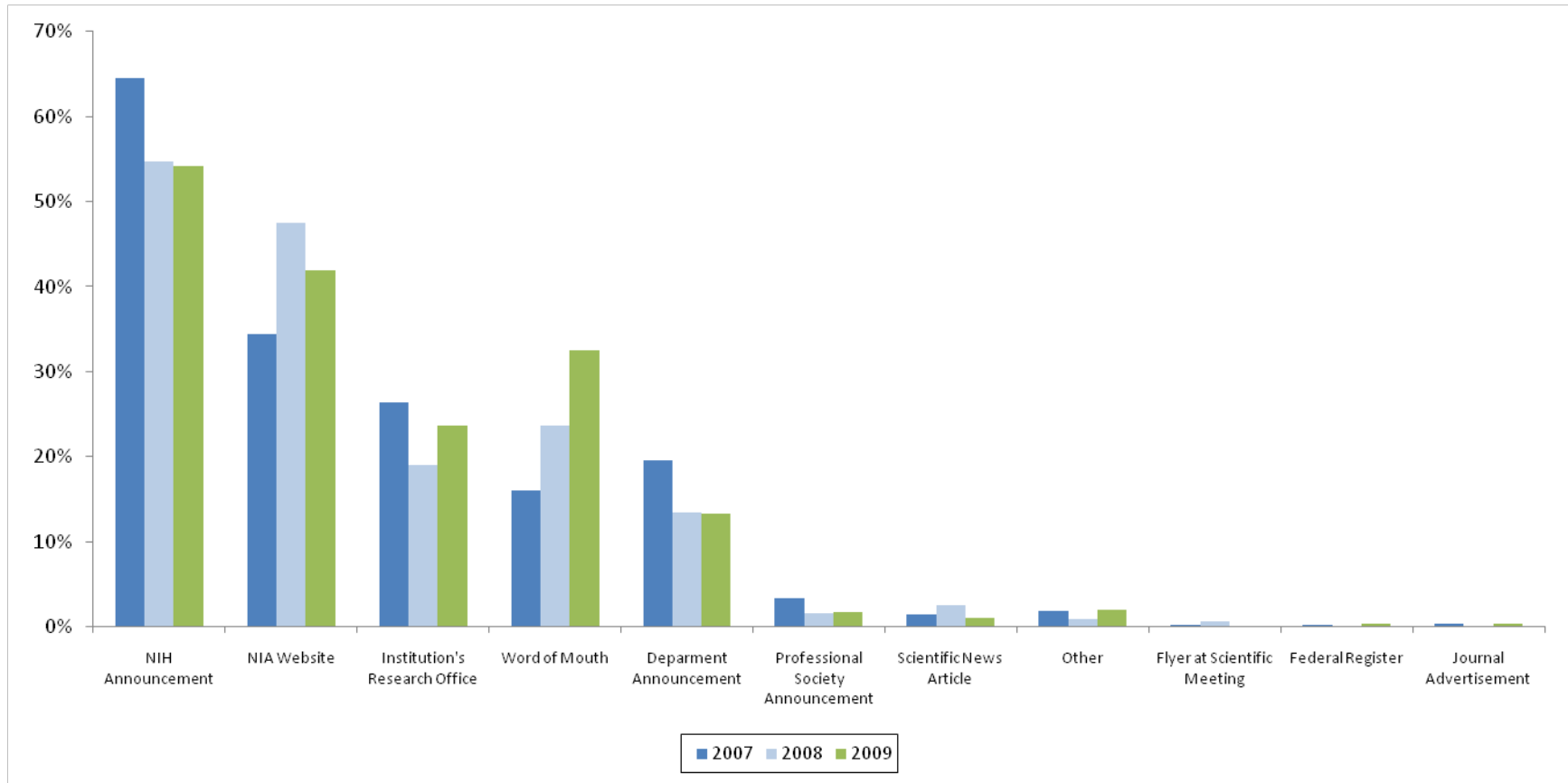
Source: NIA Applicant Survey.

Notes: Applicant responses to a survey question are presented here as the percentage of respondents by year. Respondents were able to select more than one answer. Differences between years may be due to repeat applicants being included in their latest year of application. Number of respondents = 1,686.

3.6   Program Selection Process

The selection process evolved slightly since its original design and implementation in FY 2007. Despite these changes, the goals of the NIA process remained unchanged over its first three years.

The FY 2007 selection process consisted of five steps:

1. The RFA invited applications from scientists "of exceptional creativity who propose highly innovative approaches that have the potential to produce an unusually high impact on significant contemporary problems in biomedical and behavioral research." DP2 applications from 2,181 individuals were submitted. Administrative review by NIA staff revealed that 28 were incomplete or ineligible.
2. In June 2007, external reviewers were introduced to the program and the selection process via a 15-minute orientation phone conference and written guidelines sent to them electronically. A total of 197 external reviewers scored 2,153 applications on a 5-point scale for each of the review criteria and assigned Top 4 votes to the four applications they felt were the most deserving. Each application was scored independently by three reviewers, all of whom were within the general research area of the applicant. The review criteria were as follows:

    a. *The scientific problem to be addressed:* The biomedical or behavioral significance/ importance of the problem; the likelihood that, if successful, the project will have a truly significant impact on this problem.
    b. *Innovativeness of the research proposed:* Evidence that the proposed approaches are significantly more innovative and creative than would normally be expected, especially for a new investigator, and evidence that the investigator has considered and addressed the potential risks and challenges.
    c. *Investigator qualifications:* Evidence of the investigator's creativity and potential for innovation, and the commitment of the investigator to devote 30% or more of his/her research effort on the New Innovator Award project.

3. The highest scoring applications[35] were then reviewed by NIA program leadership and a selection of directors of NIH institutes and centers (ICs), who ranked the applications into three tiers of roughly equal size. In FY 2007, a total of 78 applications were arranged into tiers. The top tier was absolutely recommended for funding, and candidates from the middle tier were also considered if funds were available.
4. This ranking was then sent to the Advisory Committee to the Director (ACD) for approval.
5. The NIH Director made the selection of 30 awardees based on the final ranking.

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[35] Within the subset of the highest-scoring applications, program leadership stated that they increased the number applications that advanced as finalists to include underrepresented groups—which included minorities and research areas not typically funded by NIH.

3.7   Evolution of Program Design and Implementation

The NIA program design remained unchanged across the first three years of the program. The minor changes that were made to the program implementation included modifications to the required effort commitment, the definition of new investigator, the research areas, and, more significantly, the number and type of review stages for awardee selection in FY 2009.

3.7.1   Change in Required Effort Commitment in 2008

In the first year of the NIA program, awardees were expected to commit 30% of their research effort to activities supported by the NIA, according to the 2007 RFA. In FY 2008, the required effort commitment was reduced to 25%. Program leadership stated that this was mainly because many NIA awardees were also recipients of NIH "K" Awards,[36] which required a 75% effort commitment.[37]

3.7.2   Change in Definition of "New Investigator" in 2008

In 2008, the NIA program changed its definition to be consistent with the NIH's new definition for "early stage investigators."

> In order to address both the duration of training and to protect the flux of new investigators, the NIH announced a new policy in fiscal year 2009 involving the identification of Early Stage Investigators (ESIs). ESIs are New Investigators who are within 10 years of completing their terminal research degree or within 10 years of completing their medical residency at the time they apply for R01 grants. Applications from ESIs will be given special consideration during peer review and at the time of funding. Peer reviewers will be instructed to focus more on the proposed approach than on the track record, and to expect less preliminary data than would be provided by an established investigator. [38]

In general, a Program Director (PD) or Principal Investigator (PI) is considered a New Investigator if he/she has not previously competed successfully as PD/PI for a substantial NIH independent research award. Specifically, a PD/PI is identified as a New Investigator if he/she has not previously competed successfully for an NIH-supported research project other than the following early stage or small research grants or for the indicated training, infrastructure, and career awards, including the Pathway to Independence Award-Research Phase (R00).

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[36]   NIH Career Development or "K" awards are "intended to support a period of mentored or independent career development in preparation for a role as an independent researcher (mentored K), or to enable and expand the grantee's potential to make significant contributions (independent K) in the biomedical, behavioral, and clinical sciences." See NIH Policy Concerning Career Development (K) Awards, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-036.html.

[37]   Interview with NIA program leadership, January 4, 2010.

[38]   See NIH's New and Early Stage Investigator Policies, http://grants.nih.gov/grants/new_investigators/index.htm.

3.7.3   Change in Research Areas in 2008

As part of their application, NIA applicants are required to select one of ten research area designations to describe their proposed research. In FY 2007, these designations were:

1. Behavioral and Social Sciences
2. Clinical and Translational Research
3. Instrumentation and Engineering
4. Molecular Biology
5. Cellular Biology
6. Chemical Biology
7. Pathogenesis
8. Epidemiology
9. Physiology and Integrative Systems
10. Quantitative and Computational Biology

Beginning in FY 2008, Molecular Biology and Cellular Biology were combined into a single Molecular and Cellular Biology designation, Pathogenesis was eliminated, and the two new designations Immunology and Neuroscience were added. Program leadership stated these changes were made in response to feedback from applicants and reviewers, to better categorize their areas of research. The research area designations for the NDPA were also modified in FY 2008, making the final ten areas identical for both programs. The research area designations for the NIA and NDPA remained unchanged through FY 2009.

3.7.4   Changes in Application Process in 2009

The most significant change to the NIA program processes occurred between FY 2008 and FY 2009. A pre-application phase, or Phase I (X02), was added to the NIA application process in FY 2009.[39] According to NIA program staff, Phase I (X02) was added to ensure that the review process adhered to Federal Advisory Committee Act guidelines. After the changes were made, it was discovered that the original review process in fact did not violate Federal Advisory Committee Act guidelines, yet the two-stage review was retained for the FY 2010 process.

In many ways, the addition of Phase I (X02) did not substantially change the application process for applicants, but was an adminstrative change for NIH. Under this process, all applicants submitted an X02 application which was the same in form as the DP2 application in previous years. NIA staff screened X02 applications for eligibility and then Phase I (X02) external reviewers scored the X02 applications on a 5-point scale for each criterion and assigned Top 4 votes. NIA staff then ranked the applications based on scores, and the top 98 applicants selected as finalists were invited to submit DP2 applications.[40] Finalists

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[39] Interview with program staff, October 2008.

[40] The number of finalists is roughly double the number expected to be funded. Ninety-nine applications were advanced, but one finalist became ineligible during the second phase of review.

then submitted their Phase I (X02) application as a DP2 application.They were allowed to update their biosketches, but could not change anything else on the application.[41]

Phase II (DP2) external reviewers, who were a different group of individuals than the Phase I (X02) reviewers, then scored the DP2 applications on a 5-point scale for each criterion and assigned Top 4 votes. The Phase II (DP2) reviewers were selected based on their experience and were not directly matched to the scientific areas of the applicants. NIA program leadership also specifically recruited individuals who were known to be mentors to junior investigators.[42]

NIA staff then used the Phase II scores to rank applications into three tiers. This tiering was then discussed and finalized in a phone meeting with the Phase II (DP2) reviewers. This was a new component to the selection process in that external reviewers determined the ranking of the final three tiers, in a teleconference. In previous years, there was no discussion of the applications among external reviewers and the three-tiered ranking was decided by NIA program leadership and IC directors. As before, the final ranking was then sent to the Advisory Committee to the Director for approval, and finally, the NIH Director selected the awardees.

3.7.5   Increased Funding Level in 2009

The numbers of NIA awardees in FY 2007 and FY 2008 were 30 and 31, respectively. The number of awardees increased to 54 in FY 2009, as a boost in NIH funding from the American Recovery and Reinvestment Act (ARRA) provided additional funds in other areas, enabling a higher number awards that year. Based on data from IMPAC II and from interviews with NIA staff, nine awards in FY 2009 were issued with ARRA funds. Three of these awards were later revised and reissued with non-ARRA funds,[43] for a total of six ARRA-funded awards. With ARRA funds, Dr. Francis Collins, the Director of NIH beginning in 2009, was able to award finalists who had proposed projects that were aligned with his strategic goals for how stimulus funding should be invested at NIH.[44]

3.7.6   Changes in Final Award Selection Strategy

In FY 2008, to increase the amount of available funding, the NIH Director gave individual ICs the opportunity to co-fund one-third of the award amount on any projects they were interested in supporting. This strategy resulted in 14 awardees being co-funded by ICs that year. In other years of the program, co-funding by ICs was negligble (1 in FY 2007 and 3 in FY 2009). ICs who cofunded included: National Institute of General Medical Sciences (8 co-funded awards); National Institute on Aging (2); National Heart, Lung, and Blood Institute (2); National Institute of Diabetes and Digestive and Kidney Diseases (1); National Institute on Drug Abuse (1); National Institute of Biomedical Imaging and

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[41] Interview with NIA program leadership, January 4, 2010.

[42] Interview with NIA program leadership, January 4, 2010.

[43] These awardees' projects would have required use of funds outside the U.S., which is prohibited for ARRA resources.

[44] E. Dolgin, "Collins sets out his vision for the NIH," *Nature News*. Published online August 18 , 2009. Retrieved November 4, 2010, from http://www.nature.com/news/2009/090818/full/460939a.html.

Bioengineering (1); National Institute on Alcohol Abuse and Alcoholism (1); National Institute of Neurological Disorders and Stroke (1), and National Institute of Mental Health (1).

Exhibit 9 shows the selection process changes made during the first three years of the program.

Exhibit 9. Aspects of NIA Program Implementation, FY 2007–2009

Aspect of New Innovator Award	FY 2007	FY 2008	FY 2009
Awards per Year	30	31	54 (6 ARRA-funded)
Size of Award	$1.5 M over five years	Same as previous year	Same as previous year
Date of RFA/PA Release	March 9, 2007	November 9, 2007	October 23, 2008 (X02); October 27, 2008 (DP2)
Wording of emphasis on women and minority groups given in PA or RFA	"Women and members of groups underrepresented in biomedical or behavioral research are especially encouraged to apply."		"Women and individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support" (X02); same as previous year (DP2)
Career Stage Requirements	Applicants must hold an independent research position at a US institution. They also must have received their most recent doctoral degree or completed their medical internship and residency within 10 years of NIA application due date. Applicants must also meet the definition of "new investigator," which is defined as those applicants who have never been a PI on an R01 or equivalent NIH grant (e.g., R23, R29, R37, U01), or leader of a P01 or center grant peer-reviewed project.		
Stated Purpose of Award	The NIA aims "to support exceptionally creative new investigators who propose highly innovative approaches that have the potential to produce an unusually high impact."	The NIA aims to "support a small number of new investigators of exceptional creativity who propose bold and highly innovative new research approaches that have the potential to produce a major impact on broad, important problems in biomedical and behavioral research."	
Proposal Length	10-page maximum	Same as previous year	10-page maximum (both X02 and DP2)
Preliminary Data	Not required	Same as previous year	Same as previous year
Biographical Sketch	2-page maximum	Same as previous year	Same as previous year
Letters of Reference	Neither required nor accepted	Same as previous year	Same as previous year
Detailed Budget Description	Neither required nor accepted	Same as previous year	Same as previous year
Effort Commitment	At least 30% of research effort to activities supported by the New Innovator Award	At least 25% of their research effort each year to activities supported by the New Innovator Award	
Method of Application Submission	Submitted application one time	Same as previous year	Submitted pre-application (X02); if chosen as finalist, re-submitted application (DP2)
Number of External Reviewers per Candidate	3	Same as previous year	3 (XO2); 3 (DP2)

Aspect of New Innovator Award	FY 2007	FY 2008	FY 2009
Possible "Area of Science" Designations	• Behavioral and Social Sciences Cellular Biology • Chemical Biology • Clinical and Translational Research Epidemiology • Instrumentation and Engineering • Molecular Biology • Pathogenesis • Physiology and Integrative Systems Quantitative and Computational Biology	• Behavioral and Social Sciences Chemical Biology • Clinical and Translational Research Epidemiology • Immunology • Instrumentation and Engineering • Molecular and Cellular Biology • Neuroscience • Physiology and Integrative Systems • Quantitative and Computational Biology	Same as previous year
Review Criterion 1	Scientific problem to be addressed: importance of the problem and likelihood of major impact		
Review Criterion 2	Innovativeness of the research proposed, especially considering the researcher is a new investigator		
Review Criterion 3	Investigator qualifications: evidence of creativity, ability to meet effort commitment		
Number of Applications Selected at each Stage of the Review Process	• 2,181 individuals submitted an application; NIH administrative review revealed 28 were incomplete or ineligible • 2,153 applications reviewed by a group of 197 external reviewers; scored on a 5-point scale; Top 4 votes assigned • 70 applications selected by program leadership to be reviewed by several IC directors • IC directors provided comments and placed applications into three roughly equal tiers • Final ranking sent to Advisory Committee to the Director (ACD) for approval • Director made final selection of 30 awardees, announced in September 2007	• 586 individuals submitted an application; NIH administrative review revealed 8 were incomplete, ineligible, or withdrawn • 578 applications reviewed by a group of 92 external reviewers; scored on a 5-point scale; Top 4 votes assigned • 78 applications selected by program leadership to be reviewed by several IC directors • IC directors provided comments and placed applications into three roughly equal tiers • Final ranking sent to ACD for approval • Director made final selection of 31 awardees, announced in September 2008	• 416 individuals submitted an X02 pre-application • 411 applications reviewed by a group of 68 external reviewers; scored on a 5-point scale; Top 4 votes assigned • 98 applicants selected by program leadership to submit DP2 application • 98 applications reviewed by a different group of 16 external reviewers; scored on a 5-point scale; Top 4 votes assigned • NIA program staff placed applications into three tiers and discussed the tiers with external reviewers in a conference call • Final ranking sent to ACD for approval • Director made final selection of 54 awardees, announced in September 2009

Aspect of New Innovator Award	FY 2007	FY 2008	FY 2009
Essay Content Guidelines	*Project description:* What is the scientific problem that will be addressed, and why is this important? What is the likelihood that, if successful, the result will have a significant impact on the problem? Why is the planned research uniquely suited to the stated goal of the New Investigator Award program, rather than a traditional grant mechanism? *Innovativeness:* What are the approaches you plan to take and what will you do if they are not successful? What is the evidence to demonstrate that the approaches proposed are significantly more innovative than would normally be expected, especially for a new investigator? *Investigator qualifications:* What evidence supports your claim of innovativeness and creativity in your research? For example, what qualities do you have that might demonstrate your inclination to challenge paradigms and take intellectual risks; your ability to develop unique collaborations, to integrate diverse sources of information, and to develop novel approaches when new challenges or opportunities arise; and your persistence in the face of failure?	*Project description:* Describe the scientific problem that you propose to address, its importance, and how solving this problem would have a major impact on a broad area of biomedical/behavioral science. Why is the planned research uniquely suited to the New Investigator Award program, rather than a traditional grant mechanism? How is this project distinct from other research that may be supported in your laboratory? Innovativeness: State clearly and concisely what makes your project unusually innovative. If the approaches entail a high degree of risk, what will you do if these approaches are not successful? Investigator qualifications: Provide evidence to support your claim of innovativeness and creativity in your research. For example, what personal qualities and experiences demonstrate your inclination to challenge paradigms and take intellectual risks, develop unique collaborations, integrate diverse sources of information, or develop novel approaches when new challenges or opportunities arise?	Same as previous year

Source: NIA 2007 Request for Applications: http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-07-009.html; NIA 2008 Request for Applications: http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-08-014.html; NIA 2009 Request for Applications: http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-09-003.html.

4.   Characteristics of the NIA Participants

This chapter describes the characteristics of the individuals who participated in the NIA program in the first three years. The data presented were primarily collected from the NIH database, IMPAC II, the survey of all NIA applicants, and curricula vitae of the investigators where available via their personal websites. Comparisons made in this chapter were tested for statistical significance.

4.1   Characteristics of Applicants

This section presents data on the applicant characteristics, including number of repeat applicants, gender, race and ethnicity, degree and seniority (years since receiving most recent degree), and previous NIH funding.

4.1.1   Repeat Applicants and Overlap with NIH Director's Pioneer Award

Over the first three years, 2,786 individuals applied to the NIA program. Many individuals applied in multiple years, resulting in a total of 3,142 applications. Two hundred and eighty-six applicants (9%) applied in exactly two years, and 35 applied in all three years (Exhibit 10). After the first year of the NIA, 35 (30%) out of the 85 awardees in FY 2008–2009, were repeat applicants (Exhibit 11).

Exhibit 10. NIA Applicants in Each Year, FY 2007–2009
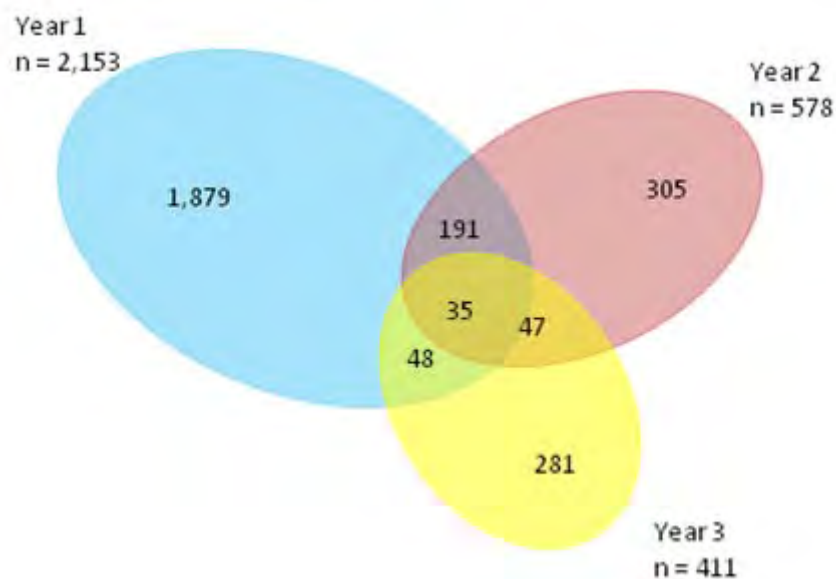
Source: Applicant information was collected from IMPAC II.
Note: The Venn diagram shows applicant participation in each year of the NIA.

Exhibit 11. Repeat Participation of NIA Applicants, FY 2007–2009

Fiscal Year	Number of First-Time Applicants (% of Total Applicants)	Number of Repeat Applicants (% of Total Applicants)	Number of First-Time Applicants Winning (% of Total Awardees)	Number of Repeat Applicants Winning (% of Total Awardees)
2007	2,153 (100%)	N/A	30 (100%)	N/A
2008	352 (61%)	226 (39%)	15 (48%)	16 (52%)
2009	281 (68%)	130 (32%)	35 (65%)	19 (35%)
Total	2,786 (89%)	356 (11%)	80 (70%)	35 (41%)*

Source: Applicant information was collected from IMPAC II, and organized into a STPI database.

* The total percentage of repeat applicants awarded (41%) was calculated as the number of awardees who were repeat applicants (35) out of the number of awardees in FY 2008–2009 (85), since it was not possible for awardees in the first year to be repeat applicants.

Over the first three years, 71 NIA applicants (2.5%) also applied to the NDPA program, 4 of whom went on to receive an NDPA and 2, an NIA.

There is little evidence to suggest that reapplying to the program in subsequent years increases the odds of advancing as a finalist, or the odds of being awarded. Analysis showed that during the FY 2008 process, the odds of becoming an awardee were marginally higher when applying to the program as a re-applicant than as a first-time applicant (Exhibit 12). In FY 2009, applying as a re-applicant did not increase odds of advancing to the finalist round or of being awarded.

**Exhibit 12. Odds of a Re-applicant Advancing as a
Finalist or an Awardee Compared to a First-Time Applicant**

Year	Condition	Odds Ratio	95% Exact Confidence Interval	
2008	Odds of advancing as a finalist	1.62	0.96	2.70
2008	Odds of being awarded	2.31	1.04	5.13
2009	Odds of advancing as a finalist	1.04	0.62	1.73
2009	Odds of being awarded	1.20	0.62	2.27

Source: STPI analysis based on NIA scoring data.

Notes: Odds ratios can be interpreted as having an effect only when the confidence interval (CI) contains results in the same direction (i.e., both greater than 1 or both less than 1). Thus, since the confidence interval for the odds of being awarded as a re-applicant in FY 2008 were both greater than 1, it can be concluded that re-applicants were 2.31 times more likely to have been awarded that year than other finalists who were applying to the NIA for the first time. The 95% Exact Confidence Interval columns correspond to the range of possible odds ratio values (at 95% confidence) given the sample population. Exact estimation of the confidence interval was used, rather than approximations, due to small sample sizes. An odds ratio <1 indicates the odds were less likely, and an odds ratio >1 denotes the odds were more likely.

4.1.2 Gender

Across all years, women have comprised approximately one third of the total NIA applicant pool; the percentage of women applying to the NIA has ranged from a low of 26% in FY 2008, to a high of 36% in FY 2007 (Exhibit 13). In the first three years of the program, there were 78 female finalists (32% of all finalists), and 42 female awardees (37% of all awardees). There was not a significant difference between

the total number of female finalists and awardees and the expected number based on the total applicant pool.[45]

Exhibit 13. Gender Distribution of NIA Applicants, Finalists, and Awardees, FY 2007–2009
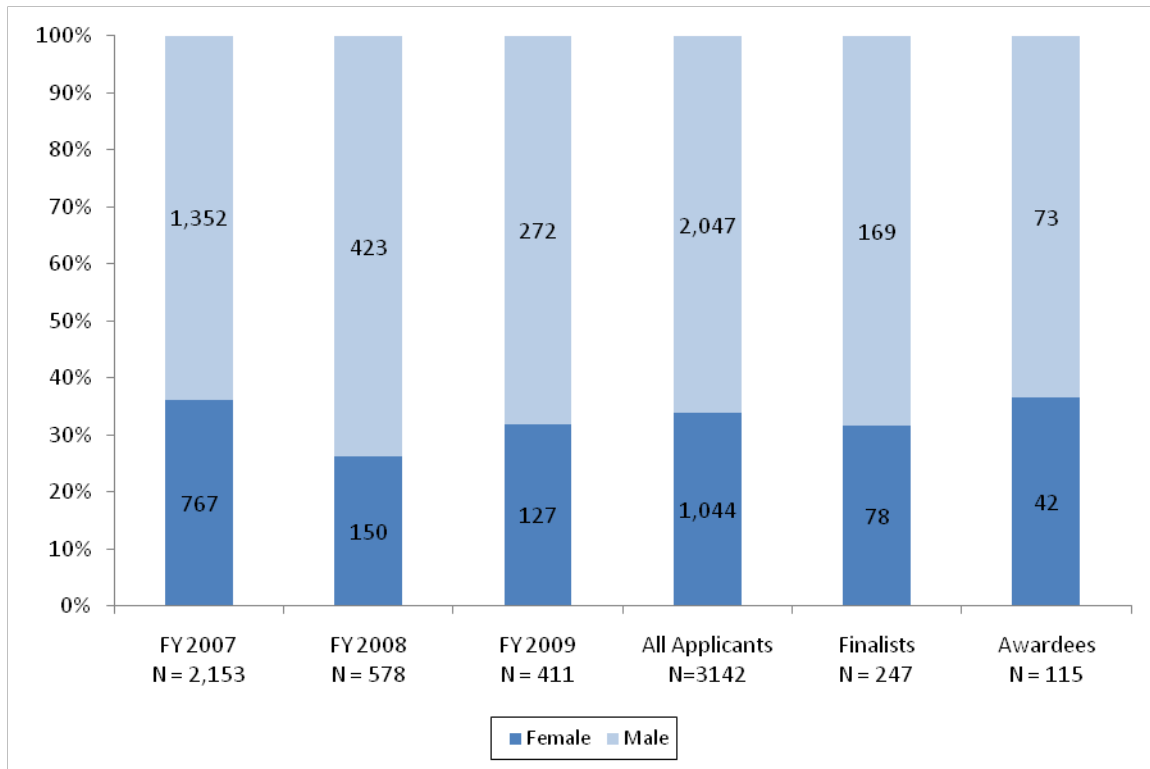
Source: IMPAC II, and applicant survey.

Notes: This graph shows percentage distributions of the gender of applicants in each year. Gender data for less than 2% of applicants (51 applicants) was unknown, and is not shown in the graph.

4.1.3   Race and Ethnicity

Self-reported race and ethnicity data for 1,554 (56%) of the 2,786 individuals who applied to the NIA between FY 2007–2009 were obtained through the survey of applicants (Exhibit 14). Of the individuals who responded to the survey question, 56% were White, 27% were Asian, 3% were Black or African American, and less than 1% were American Indian or Alaska Native or Native Hawaiian or other Pacific Islander. The remaining 13% of respondents did not disclose their race. There was not a significant difference between the race distribution of the total applicant pool and that of the finalists or the awardees.[46]

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[45]   Fisher's Exact Test, p = 0.6293.

[46]   Fisher's Exact Test, p = 0.65, omitting those who withheld their race.

Exhibit 14. Race of NIA Survey Respondents, FY 2007–2009
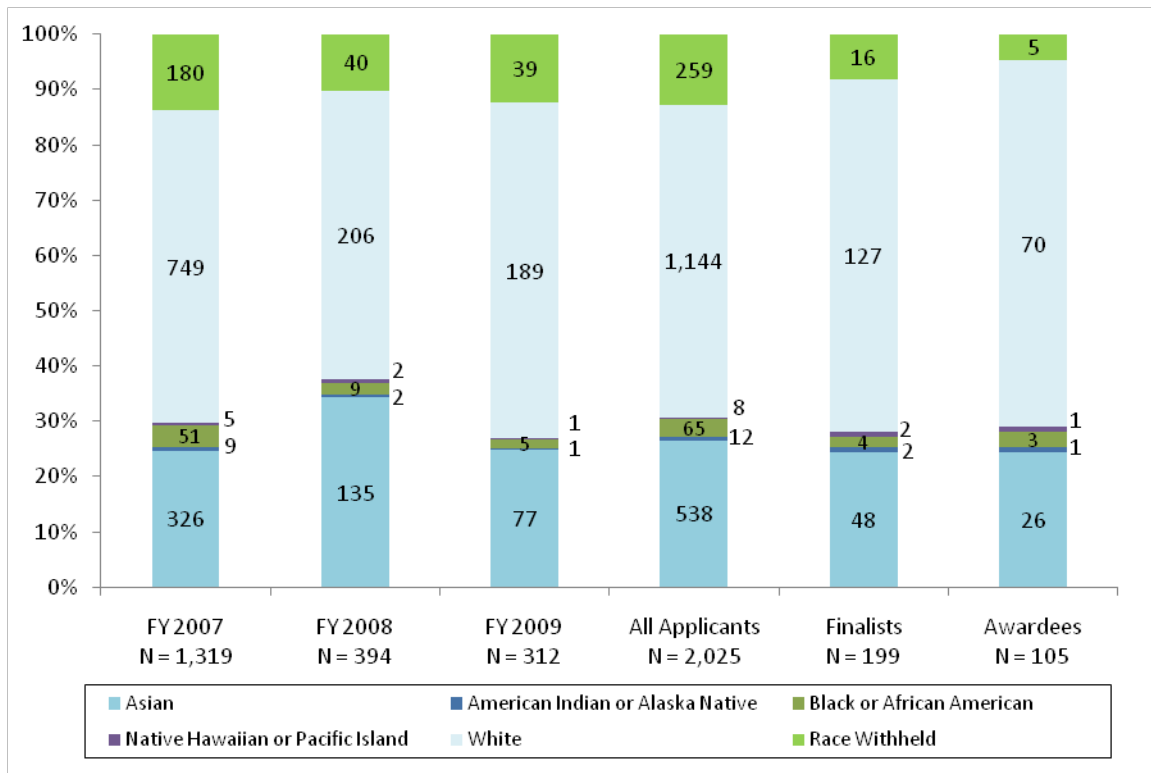
Source: Applicant race data were self-reported through the survey.

Note: The graph shows percentage distributions of reported race by applicants who completed the survey. Applicants were able to select all races with which they identified.

There was not a statistically significant difference between the distribution of the ethnicity of the finalists and awardees compared to that of the total applicant pool.[47] Overall, 81% of the applicants identified as Not Hispanic or Latino, 5% were Hispanic or Latino, and 15% did not disclose their ethnicity (Exhibit 15).

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[47] Fisher's Exact Test, p = 0.45, omitting those who withheld their ethnicity.

Exhibit 15. Ethnicity of NIA Survey Respondents, FY 2007–2009
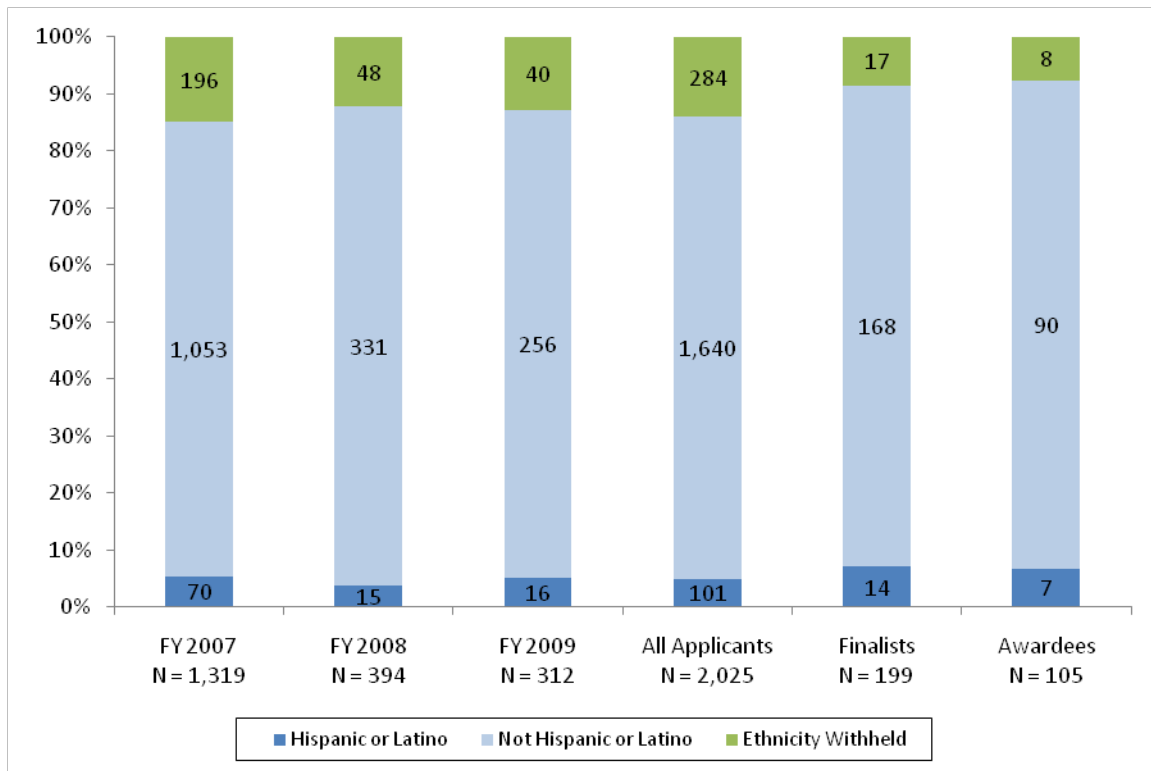
Source: Applicant ethnicity data were self-reported through the survey.

Note: The graph shows percentage distributions of reported ethnicity by applicants who completed the survey.

4.1.4 Doctoral Degrees and Seniority

Degree data were available for 2,293 (82%) of the 2,786 applicants in the first three years of the program. The majority of NIA applicants hold PhDs (64%), while 9% hold MDs and 10% hold MD/PhDs (Exhibit 16). The degree distribution of awardees was significantly different from that of the total applicant pool, as fewer MDs received NIA awards than expected based on the total applicant pool.[48]

Data on their most recent doctoral degrees were available for 1,994 (72%) of the 2,786 individuals who applied to NIA in the first three years of the program. There were no significant differences between the distribution of the number of years since the last doctoral degree for awardees and finalists compared to that of applicants in each year.[49] See Exhibit 17.

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[48] Fisher's Exact Test, p = 0.002, omitting applicants for whom degree data were unavailable.

[49] Fisher's Exact Test, p = 0.575 for FY 2007, p = 0.722 for FY 2008, and p = 0.856 for FY 2009, omitting applicants for whom degree data were unavailable.

Exhibit 16. Doctoral Degrees of NIA Applicants, FY 2007–2009
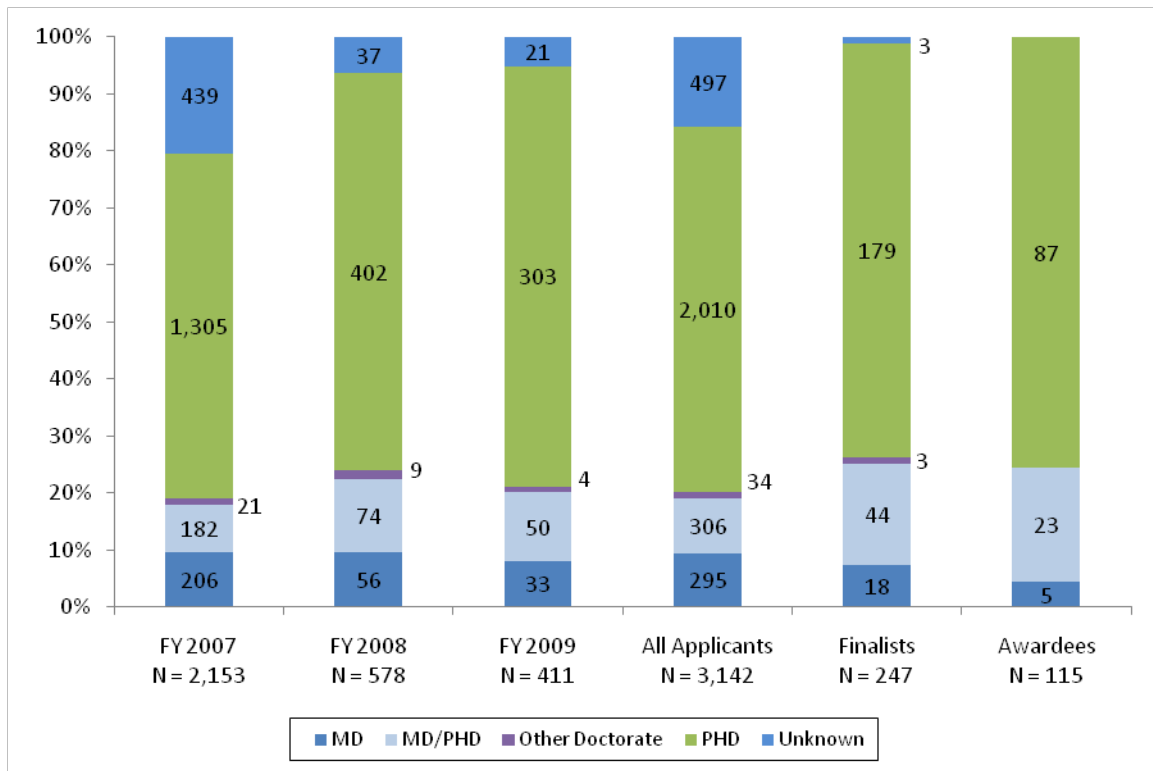
Source: The doctoral degree information for applicants was collected from IMPAC II and was self-reported through the applicant survey.

Notes: The graph shows percentage distributions of doctoral degrees of applicants. The doctoral degree information for approximately 18% of NIA applicants (primarily from FY 2007) was unknown. "Other Doctorate" degrees included: DPM, DVM, PharmD, DPH, DNP, DNS/DNSc, DDS, DDM/DMD, DScD, DSc/ScD, and OD.

Exhibit 17. Years Since Most Recent Degree of NIA Candidates, FY 2007–2009
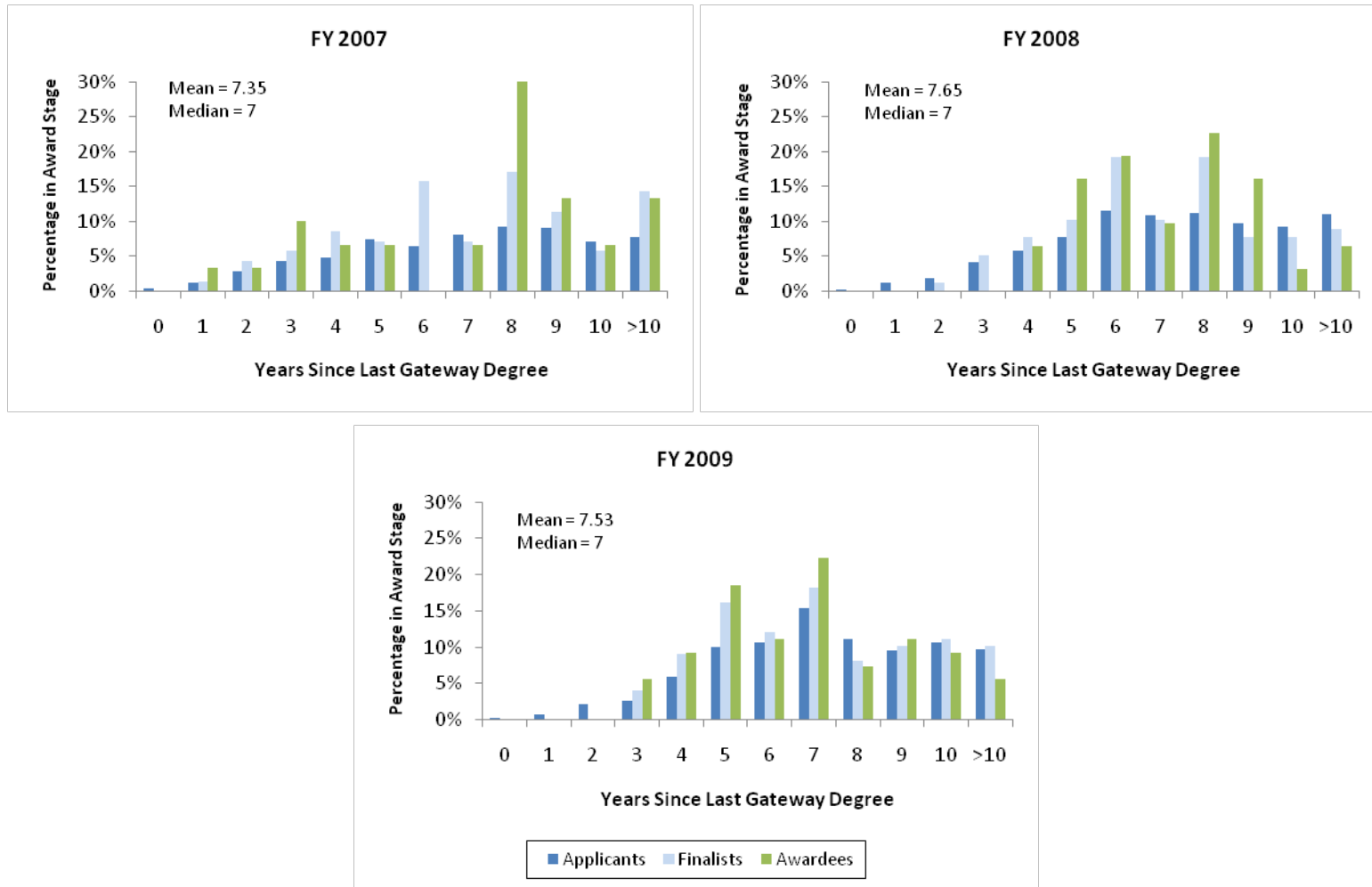
Source: The year of applicants' most recent doctoral degree was collected from IMPAC II and from the applicant survey.

Notes: This graph shows percentage distributions of the seniority of applicants. Unknown data are not included. Exceptions were made on a case-by-case basis for individuals who requested to extend their Early-Stage Investigator status, which is shown by the applicants who were more than 10 years out from the most recent doctoral degree at the time of applying to the NIA.

4.1.5 Previous National Institutes of Health Funding and Concurrent Applications to R01s

The NIA was created to support highly creative, new investigators, who propose exceptionally creative research ideas. As designed, the NIA is meant to complement the traditional R01 funding and other mechanisms at NIH, which serve as the predominant source of research funding for new investigators.[50] Many NIA applicants simultaneously applied for both the NIA and R01 funding. In FY 2007, 541 of the 2,153 applicants (25%) applied for both; in FY 2008 and FY 2009, 82 of 578 (14%) and 131 of 411 (31%), respectively, applied for R01 funding in the same year as their NIA application.

At the time of applying to the NIA, roughly three-quarters of applicants had not previously received NIH funding. Of the NIA applicants who had received NIH funding before applying (25%), "K" awards and F32 postdoctoral fellowships were the most common sources of funding (Exhibit 18). Also, about 5% of NIA applicants previously held an R21 grant. An analysis showed that having previously received an R21 increased the odds of being awarded as an NIA finalist (data not shown), as these investigators were 0.18 times more likely to have been awardees over other finalists.

4.2 Characteristics of the Applications

This section describes some characteristics of the applications, and the individuals applying to the NIA program in FY 2007–2009.

4.2.1 Research Areas

As part of the application process, applicants were required to categorize their research into one of ten areas. Research area options were modified in FY 2008 (see Exhibit 19).[51] In the first three years, the Molecular and Cellular Biology[52] and Clinical and Translational Medicine were the most common research areas, representing 20% and 22% of all proposed projects, respectively. The least common research areas were Immunology, Neuroscience, and Epidemiology, representing 2%, 3%, and 3% of all applications, respectively. Immunology and Neuroscience were both added in FY 2008.

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[50] The NIH Director's New Innovator Award Overview, http://nihroadmap.nih.gov/newinnovator/.

[51] Also described in Chapter 3.

[52] For the purpose of this chart, for applicants in 2007, the Molecular Biology and Cellular Biology designations were grouped together.

Exhibit 18. Percentage of NIA Applicants, Finalists, and Awardees Who Previously Received NIH Funding

NIH Grant	2007			2008			2009		
	Applicants	Finalists	Awardees	Applicants	Finalists	Awardees	Applicants	Finalists	Awardees
At least 1 NIH funded grant	26%	33%	37%	13%	11%	16%	30%	43%	33%
At least 1 R21	5%	0%	10%	2%	0%	0%	6%	5%	11%
At least 1 R03	3%	5%	0%	2%	4%	0%	2%	0%	0%
At least 1 R01	0%	0%	3%	0%	0%	0%	3%	5%	0%
At least 1 K-award	10%	18%	20%	5%	2%	7%	4%	0%	7%
K99	0%	0%	0%	0%	0%	0%	1%	5%	0%
F31	1%	13%	3%	1%	2%	0%	1%	5%	0%
F32	8%	13%	7%	4%	4%	10%	8%	14%	9%

Source: Applicants' previous funding histories were obtained through IMPAC II.

Exhibit 19. Research Areas of NIA Applicants, FY 2007–2009
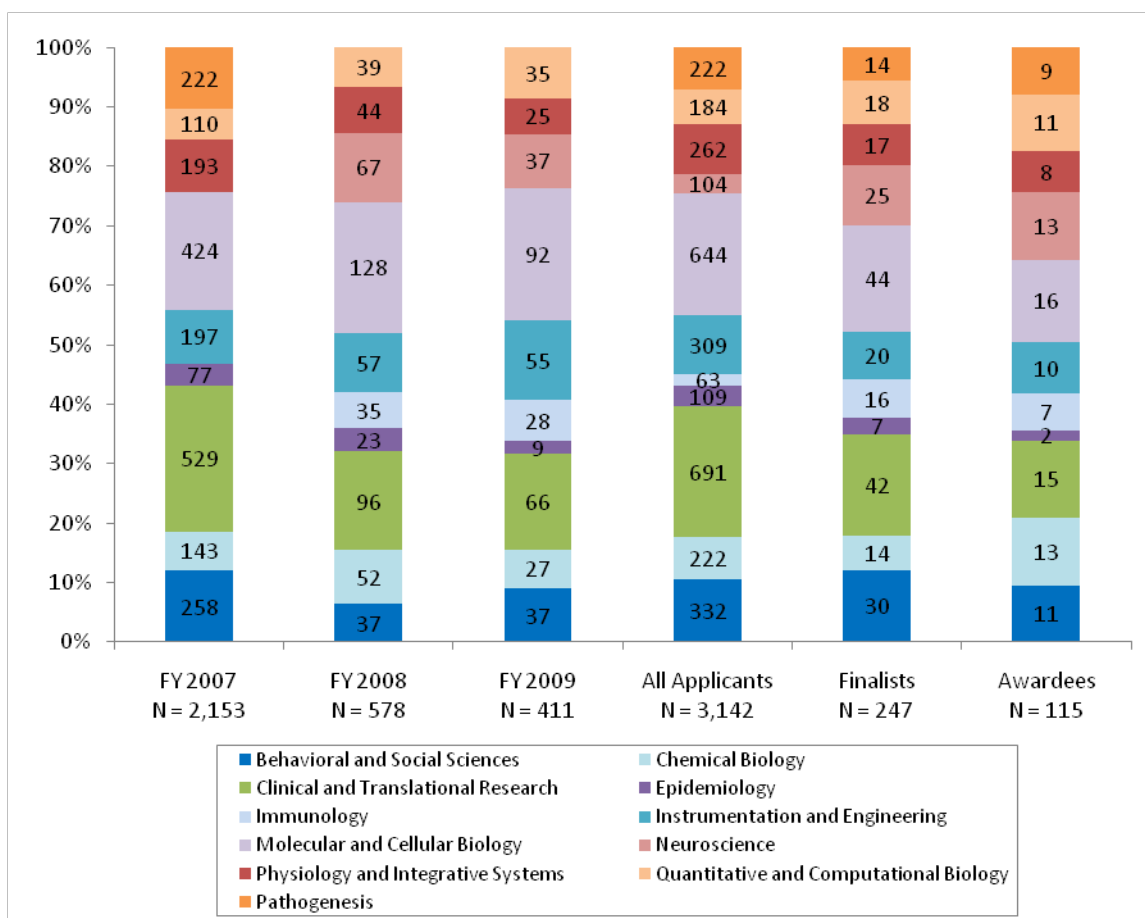
Source: Applicant information was collected from IMPAC II.

Notes: This graph shows percentage distributions of research areas of applicants. The Pathogenesis research area was eliminated after FY 2007, and Neuroscience and Immunology were added. After FY 2007, Molecular Biology and Cellular Biology were combined into the research area, Molecular and Cellular Biology. In this graph, application counts in Molecular Biology and Cellular Biology were combined for FY 2007.

4.2.2 Institutional Affiliations

Across the first three years of the NIA, 18% of applicants were from ten institutions, and the rest of the applicant pool represented 442 institutions (data not shown). Applicants in FY 2007–2009 were from institutions in all 50 states, Puerto Rico, the District of Columbia, and Kenya (Exhibit 20). Forty-two percent of awardees were from 10 institutions, which were not exactly the same as the top ten institutions represented by applications (Exhibit 21). The remaining 58% of awardees were drawn from 48 institutions (data not shown).

Exhibit 20. Geographic Distribution of Institutions of NIA Applicants and Awardees, FY 2007–2009

Source: Applicant institution information was collected from IMPAC II. Map was created using Tableau Public.

Notes: Map indicates the continental U.S. locations of applicants' and awardees' institutions. Blue circles are applicants, orange circles are awardees. This map excludes eight applicants outside the continental United States, representing Alaska, Hawaii, Puerto Rico, and Kenya.

Exhibit 21. Top Ten Most Common Institutional Affiliations of NIA Awardees, FY 2007–2009

Institutional Affiliation	Number of Awardees	Percentage of Total Awardees	Number of Applicants	Percentage of Total Applicants
Stanford University	8	7%	42	1%
University of California San Diego	7	6%	37	1%
Massachusetts General Hospital (#7)	7	6%	54	2%
University of California San Francisco (#6)	6	5%	55	2%
University of California Los Angeles (#10)	5	4%	45	1%
University of Minnesota Twin Cities	3	3%	37	1%
Johns Hopkins University (#1)	3	3%	83	3%
Massachusetts Institute of Technology	3	3%	19	1%
Yale University (#4)	3	3%	57	2%
Princeton University	3	3%	12	0%

Source: Applicant institution information was collected from IMPAC II.

Note: The numbers in parentheses indicate which institutions were ranked in the top ten most common affiliations of the total applicant pool.

4.3   Characteristics of External Reviewers

This section outlines the recruitment process for reviewers who were involved in evaluating applications for the NIA program, and summarizes the characteristics of the reviewers.

4.3.1   Reviewer Recruitment

The NIA program leadership sought to attract reviewers who were "outstanding, broad-thinking, and innovative scientists who can evaluate the novelty, creativity and potential impact of the proposed projects within the broader context of biomedical and behavioral research."[53] The program also wished to attract a diverse group of external reviewers. NIA program leadership requested the ICs to recommend individuals who could be potential reviewers for the NIA, and also drew from the same pool of reviewers for other Roadmap programs. In FY 2009, when an additional review phase was added, NIA program leadership sought reviewers who were senior investigators, and specifically recruited individuals who were known to be mentors to junior investigators.[54]

STPI collected information for the 321 reviewers from the first three years of the NIA and found that:

- Fifty-three are members of the National Academy of Sciences (NAS)
- Nine are recipients of the National Medal of Science
- Forty-one are currently, or have been at some point in their careers, Howard Hughes Medical Investigators (HHMI)
- Twenty-seven are awardees of the NDPA

4.3.2   Repeat Reviewers and Overlap with NDPA

A total of 321 external reviewers have participated in at least one year of review, though 45 individuals have served in multiple years for a total of 373 individual participation counts (Exhibit 22).

Nearly a quarter of the individuals who reviewed for the NIA overlapped with the NDPA, as 75 out of 321 (24%) participated as reviewers for the NDPA in the same year as or in a prior year to their participation for as an NIA reviewer. The breakdown of participation as an NDPA reviewer or awardee by year is presented in Exhibit 23. Over one-third of reviewers (34%) in the first year of the NIA program had previously served as reviewers for the NDPA. This was likely due to the short lead time the NIH staff had to implement the program, thus, external reviewers for NIA were recruited from the individuals who had previously participated with the NDPA. In subsequent years, the percentage of NIA reviewers who had previously been NDPA reviewers dropped from 34% in FY 2007 to 8% and 13% in FY 2008 and FY 2009, respectively.

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[53]   Letter of Invitation for New Innovator Reviewers.

[54]   Interview with NIA Program Leadership: January 4, 2010.

Exhibit 22. NIA Reviewers in each Year, FY 2007–2009
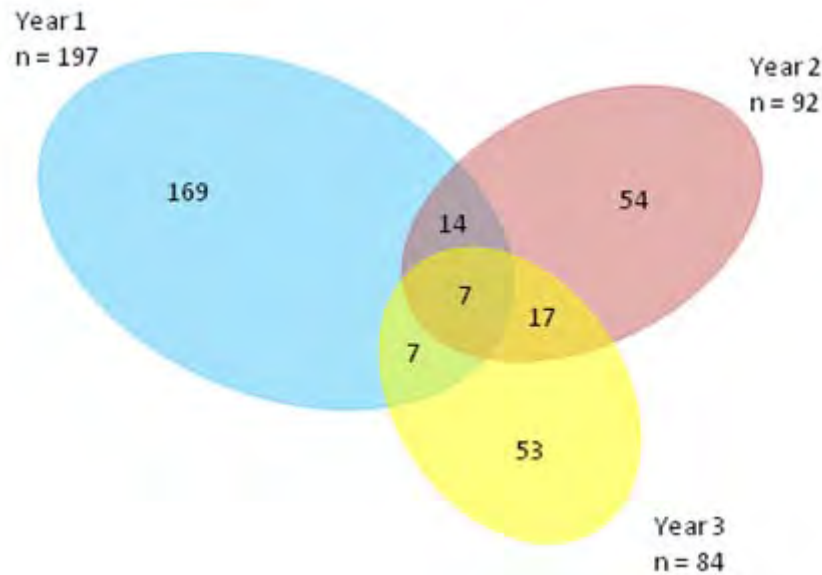
Source: Reviewer information was obtained from NIA program staff.

Note: This Venn diagram shows participation of external reviewers each year.

**Exhibit 23. Number of NIA Reviewers Who Reviewed for
NIH Director's Pioneer Award (NDPA), FY 2007–2009**

FY	Total Number of NIA Reviewers that Year	Number of NIA Reviewers Who Were Also NDPA Reviewers	Percentage of NIA Reviewers Who Were Also NDPA Reviewers	Number of NIA Reviewers Who Were NDPA Awardees	Percentage of NIA Reviewers Who Were Also NDPA Awardees
2007	197	66	34%	22	11%
2008	92	7	8%	9	10%
2009	84	11	13%	10	12%

NDPA awardees were also recruited to be reviewers for the NIA, and 27 out of 321 external reviewers (8%) had received the NDPA prior to their review for the NIA.

4.3.3 Characteristics of Reviewers

NIH used four sets of reviewers over the three years, one for each year of the program reviewed as well as an additional set for the second phase (DP2) in FY 2009. About 15% of the reviewers reviewed in more than one year. The FY 2009 Phase I (X02) and Phase II (DP2) reviewers were two separate groups of reviewers.

Overall, across all three years, the external reviewers[55] were:

- Mostly male (66% male, 34% female, Exhibit 24)
- Predominantly senior investigators (73% of reviewers obtained degrees more than 20 years ago, Exhibit 25)
- Predominately held PhDs as their doctoral degree (67% PhD, 21% MD, 10% MD/PhD, 3% Other doctorate, Exhibit 26)
- Matched the research area distribution of the applicant pool (Exhibit 27)[56]

Exhibit 24. Gender of NIA Reviewers, FY 2007–2009
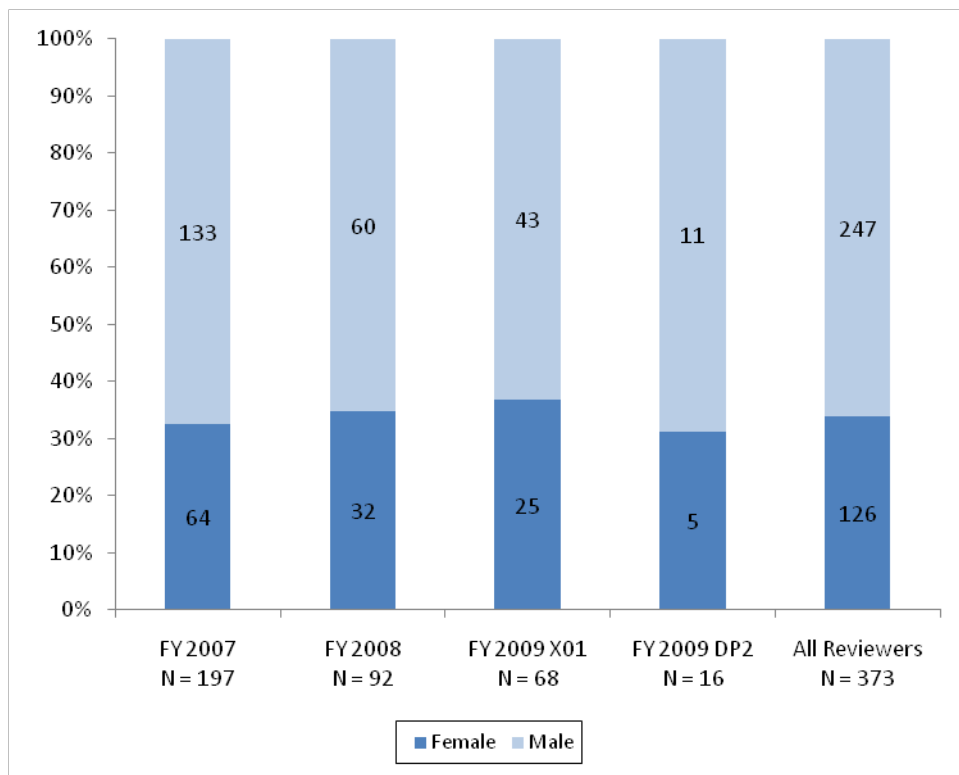
Source: Data on reviewer gender were obtained from IMPAC II and from CV analysis.

Note: The graph shows percentage distributions of the gender of reviewers.

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[55] Based on 373 reviewers, so some reviewers are counted more than once.

[56] Each NIA reviewer was meant to be matched to the area of the applicant. NIA program staff were unable to provide information on which reviewer had reviewed which application, however. STPI analyses showed that there were no significant differences between the research area distributions for reviewers and for applicants: Fisher's Exact Test, p = 1 for FY 2007; p = 1 for FY 2008, p = 0.33 for FY 2009 X02, and p = 0.14 for FY 2009 DP2.

Exhibit 25. Seniority of NIA Reviewers, FY 2007–2009
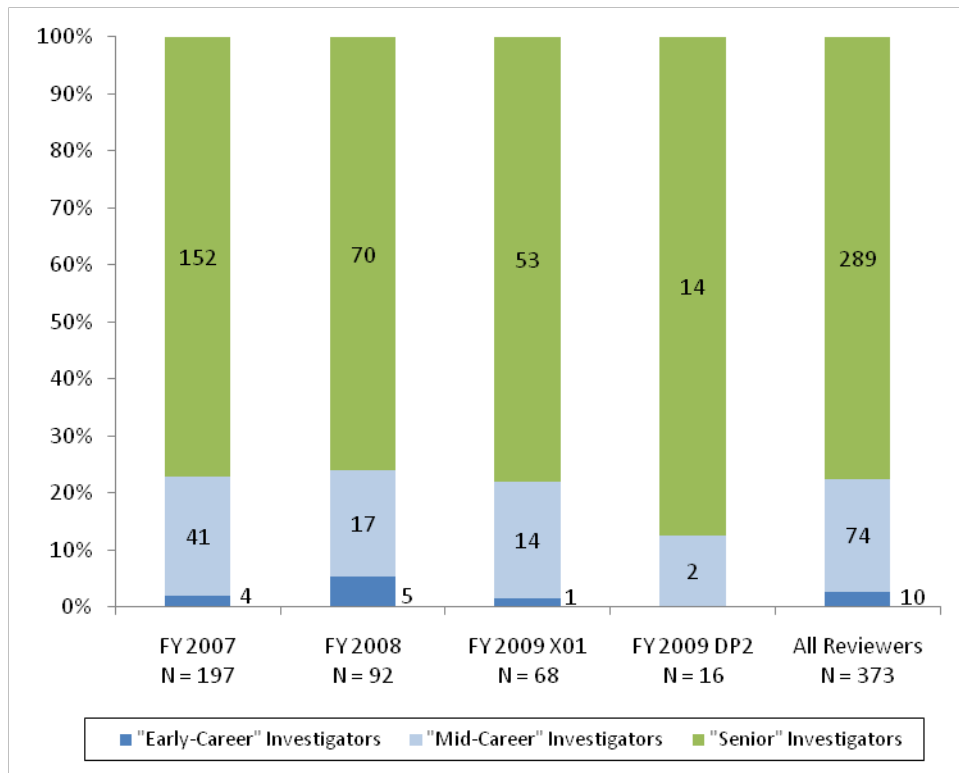
Source: Data on reviewer seniority were obtained from IMPAC II and CV analysis.

Note: The graph shows percentage distributions of the seniority of reviewers. Early-Career ≤ 10 years since first doctorate, Mid-Career between 10 and 20 years, and Senior ≥ 20 years.

Exhibit 26. Degrees of NIA Reviewers, FY 2007–2009
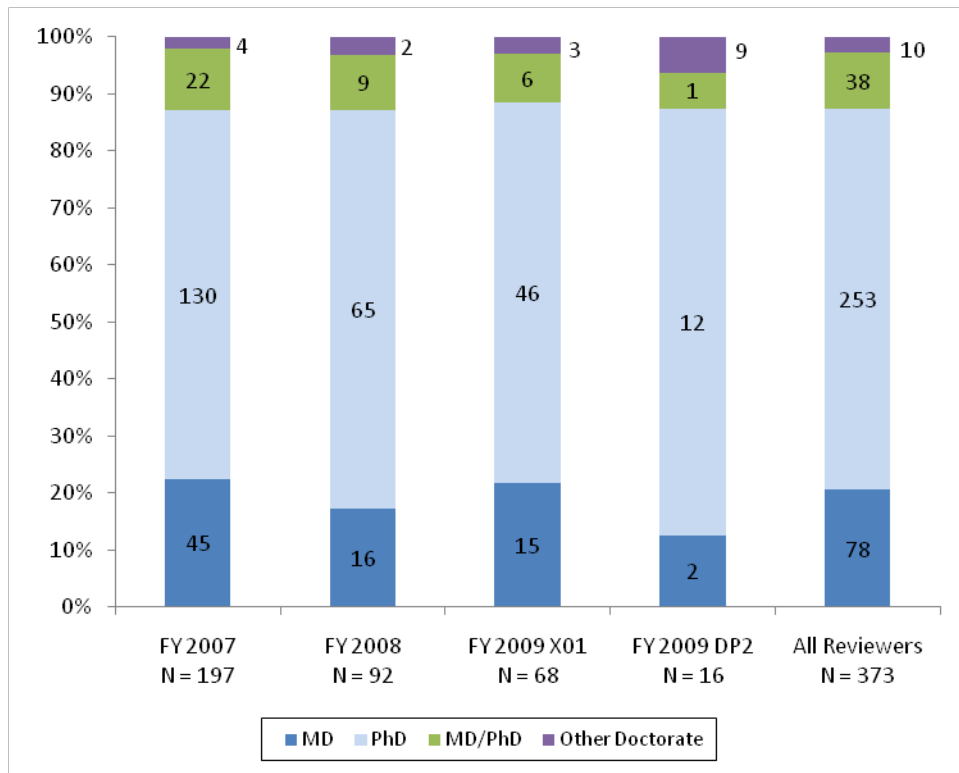
Source: Data on reviewers' degrees were obtained from personal websites and available curricula vitae.

Notes: The graph shows percentage distributions of degrees of reviewers. All doctoral degrees listed were included in the counts.

Exhibit 27. Research Areas of NIA Reviewers, FY 2007–2009
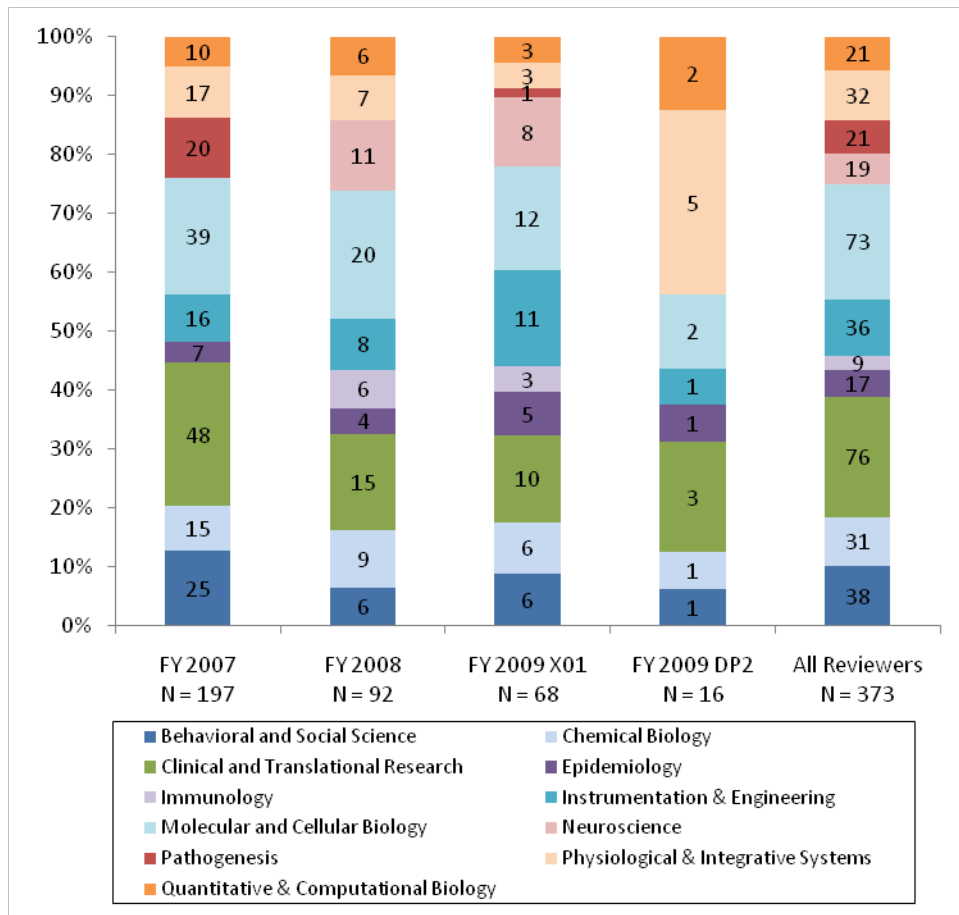
Source: Data on reviewers' research areas were obtained from NIA program staff.

Note: The graph shows percentage distributions of reviewers' research areas.

5. Perceptions of Applicants and Awardees

STPI invited all NIA applicants to share their perspectives of the NIA selection and application process through the survey of applicants. Additionally, focus groups comprising NIA awardees were convened at the 2009 and 2010 NDPA symposia in order to give attendees the opportunity to talk about their experiences with the program and application process. This chapter summarizes the key findings regarding the applicants' perceptions of the NIA program.

5.1 Perception of the NIA Program

Survey respondents were primarily drawn to the program's commitment to supporting both early-career investigators and nontraditional ideas (Exhibit 28). Other attractive aspects included the promotion of nontraditional disciplines and interdisciplinary collaborations and the guaranteed duration of funding. Awardees who attended the symposia's focus groups agreed that the flexibility of the NIA was an element they strongly appreciated. The notion that the award funds new investigators and innovative ideas with less administrative oversight than traditional grants was a strong attractant for applicants.

Exhibit 28. Applicant Survey Question: What attracted you to the NIA program?
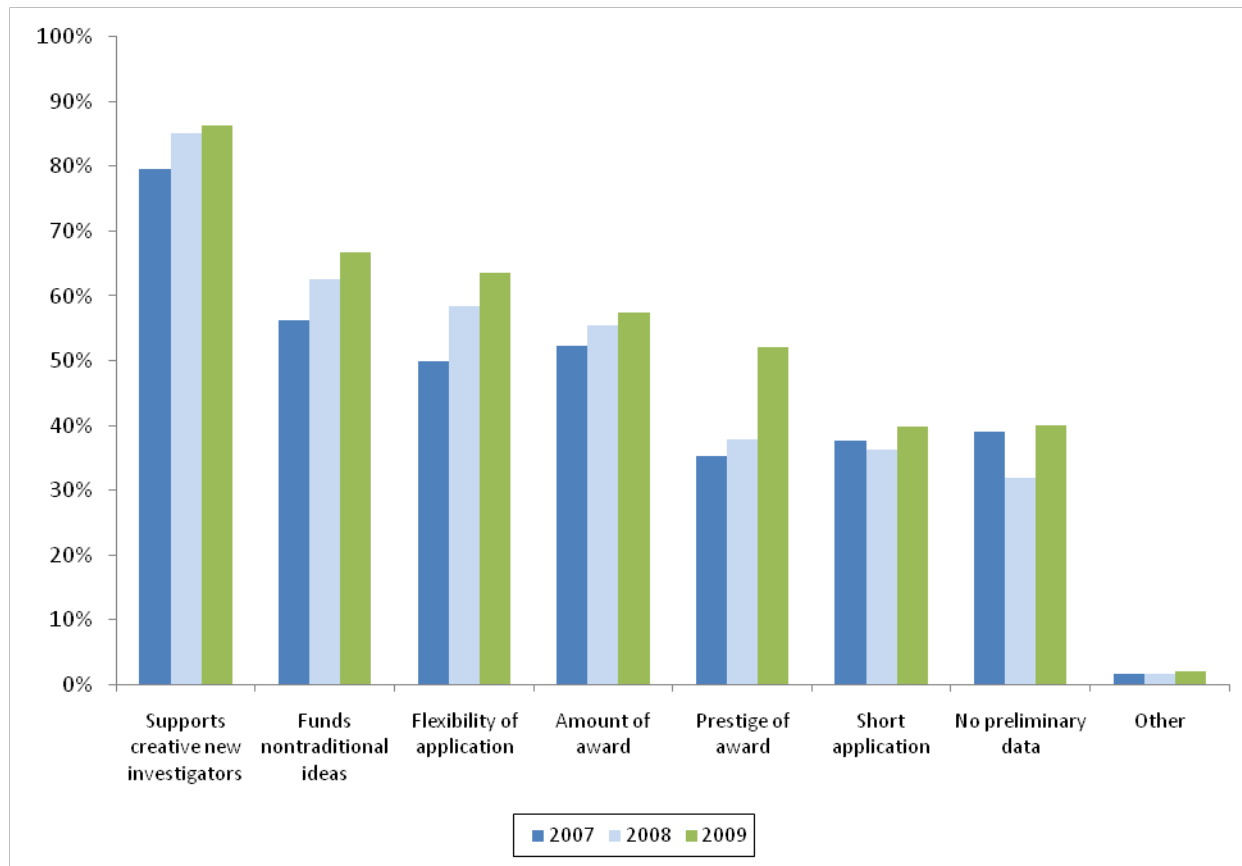
Source: NIA Applicant Survey.

Notes: Applicant responses to a survey question are presented here as the percentage of respondents by year. Respondents were able to select more than one answer. Number of respondents = 1,689.

The survey of applicants also questioned respondents about the transparency of the goals of the program. A majority of applicants thought that the RFAs/PAs were at least "somewhat clear" in describing the type of researcher and project the NIA sought to fund (Exhibit 29).

Exhibit 29. Applicant Survey Question: Was the RFA/PA clear in describing the kind of investigator or the kind of idea the program seeks to fund?
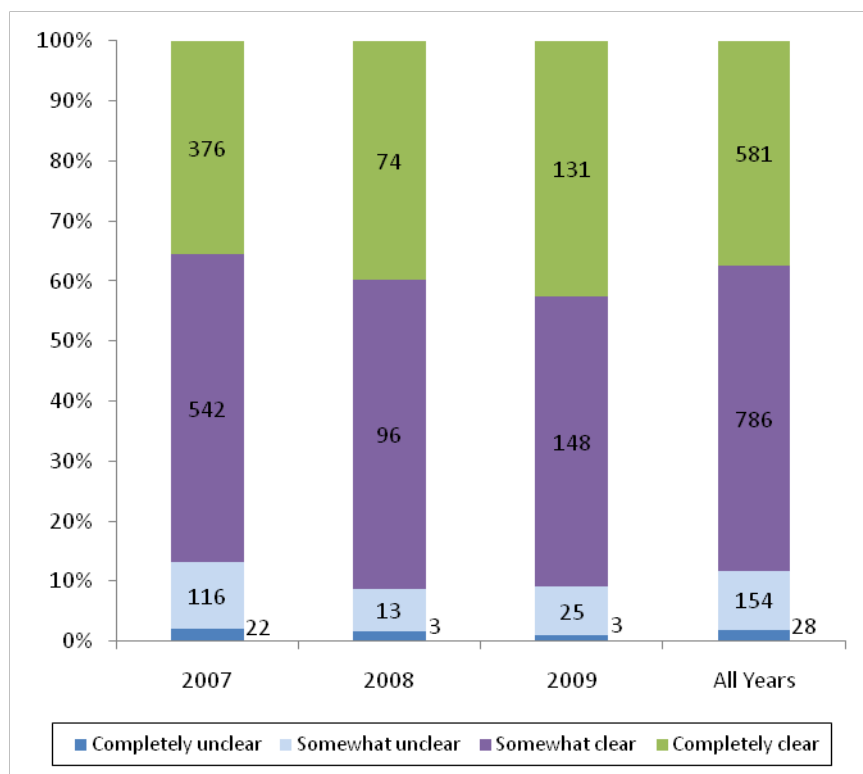
Source: NIA Applicant Survey.

Notes: The graph shows percentage distributions of applicant responses to a survey question. Number of respondents = 1,549.

When asked whether they believed the review criteria were suitable for achieving the program's goals, 58% of survey respondents affirmed the criteria were suitable, and over 90% felt they were at least somewhat suitable (Exhibit 30). When applicants did not believe the criteria were suitable, several concerns were voiced. For example, some respondents believed that the focus on the investigator's qualifications introduced a selection bias in favor of researchers affiliated with particular institutions or of certain scientific pedigrees. A blind review process was suggested as a remedy for this issue. Additionally, survey respondents were concerned by the reviewers' varying definitions of "innovation."

Exhibit 30. Applicant Survey Question: Do you believe the criteria were appropriate for achieving the goals of the NIA program?

Source: NIA Applicant Survey.

Notes: The graph shows percentage distributions of applicant responses to a survey question. Number of respondents = 1,647.

5.2   Application Materials and Requirements

5.2.1   Research Areas

Over 70% of survey respondents (72%) indicated that the ten research areas by which they had to characterize their research were adequate (Exhibit 31).

Exhibit 31. Applicant Survey Question:
Were the 10 research areas adequate to choose from?

Applicants who did not believe that the research areas were adequate offered the following feedback:

"I believe that research areas for NIA were too broad…it would be almost impossible for NIH to recruit only experts in one study section. NIH should consider…something similar to manuscript submission."

"I think the NIA had subcommittees that were too broad. Considering that the review rests heavily on one or two reviewers, it is hard to imagine reviewers having equal expertise with the broad range of projects submitted, even with a sub-specialty."

"Reviewers should be from relevant fields of study so that they can assess the impact of the proposed work."

Feedback from the applicants who were not satisfied with the research areas (28%) suggests that the categories may have been too broad.[57]

Nearly two-thirds of respondents (63%) felt they were given adequate opportunity to display their qualifications in the application, while 6% of respondents did not agree (Exhibit 32).

Exhibit 32. Applicant Survey Question: Were you given an adequate opportunity to present your idea and display your qualifications in the application?
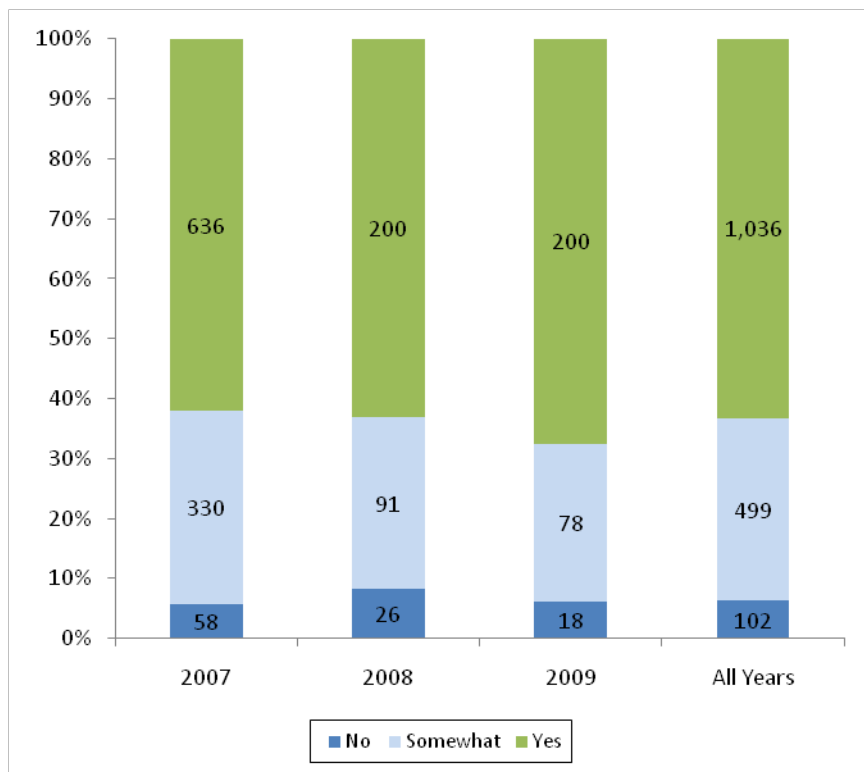
Source: NIA Applicant Survey.

Notes: The graph shows percentage distributions of applicant responses to a survey question. Number of respondents = 1,637.

Applicants who responded to the survey gave the following comments to support why they agreed or disagreed that they were given adequate opportunity to display their qualifications:

"No additional information was necessary. The least information the better so that reviewers can focus on proposal."

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[57] Similarly, 27 out of the 93 reviewers interviewed recalled being uncomfortable reviewing the applications they were assigned because they were unfamiliar with the subject area (Exhibit 42). This finding suggests that the research categories may have been too broad.

"I actually felt that the application was just right. It was straightforward to fill out and focused predominantly on the science. I appreciated that other considerations (such as facilities, budget, etc.) did not seem to be emphasized."

"I would rather have a recommendation letter system than having myself explaining how innovative I am."

"I think I would have preferred a more structured template so that I could be sure to address all the questions the reviewers might have such as timelines, etc."

"The expectations surrounding the 'innovativeness' and 'investigator qualifications' were difficult to ascertain. I do not know if I devoted too much or too little space to these components and could have or should have better developed my idea."

The respondents who did not think the applications adequately displayed their qualifications suggested that the applications could have been better structured to ensure that all the components fulfilled the reviewers' expectations. Respondents also suggested that letters of recommendation may have been a more effective way to demonstrate the qualifications and innovativeness of the investigator than the proposal essay.

5.2.2 Preliminary Data

In preparation for applying to the NIA, survey respondents most frequently reported collecting preliminary data and synthesizing literature (Exhibit 33).

Exhibit 33. Applicant Survey Question: What preliminary work did you do prior to submitting your NIA application?
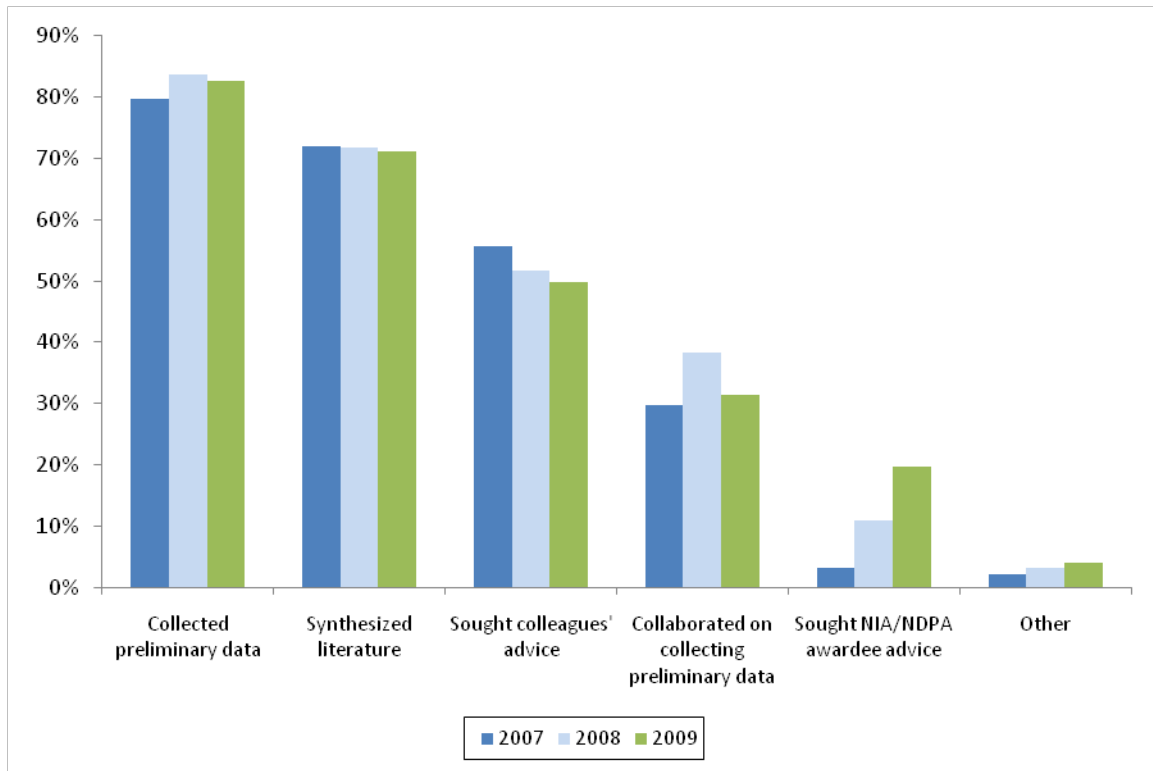
Source: NIA Applicant Survey.

Notes: Applicant responses to a survey question are presented here as the percentage of respondents by year. Respondents were able to select more than one answer. Number of respondents = 1,652.

Many of those who did not include preliminary results in their applications believed they had been penalized during the review process, and they suggested that the NIA require the data in the future.[58]

> *"It seems that some reviewers were not clear on how much preliminary data was too much, or conversely, that an idea was too risky."*

> *"Although preliminary data is not required, I felt that the applications that were funded came from investigators who [had] had a longer post-doc to publish papers and collect preliminary data. If I had known this, I would not [have bothered] applying to NIA."*

Analyses were conducted to assess whether survey respondents who reported collecting preliminary data as part of the application were more likely to advance as finalists, or win the award, compared to

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[58] Fifty-one out of 75 reviewers interviewed reported that they scored applications favorably if they included preliminary data.

those who had not. We found no evidence to show that individuals who reported collecting preliminary data had increased odds of becoming a finalist or an awardee (data not shown).[59]

5.2.3   NIA as a Distinct Funding Mechanism

Applicants were asked about the likelihood of their NIA-proposed ideas being funded by other sources. More than half of survey respondents (58%) believed that it was at least "somewhat likely" that their proposed projects could have been supported with other funding mechanisms (Exhibit 34).

Exhibit 34. Applicant Survey Question: In your opinion, what is the likelihood that your NIA-proposed research would have been supported by any other funding sources?
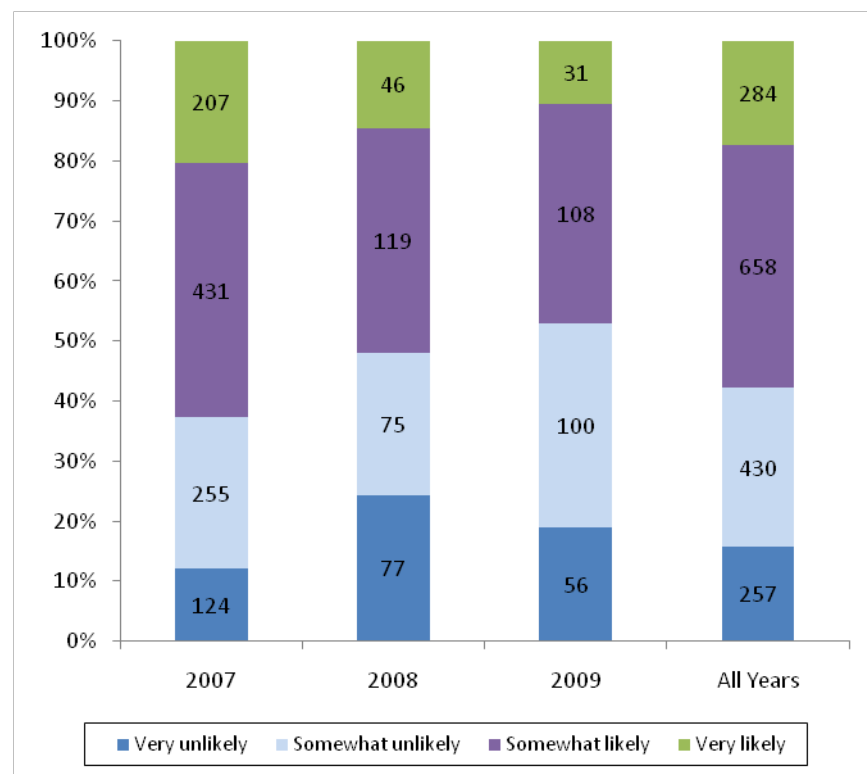
Source: NIA Applicant Survey.

Notes: The graph shows percentage distributions of applicant responses to a survey question. Number of respondents = 1,629.

Additionally, more than half of applicants (53%) across the first three years reported that their proposed project was not a significant departure from their previous research focus (Exhibit 35). Finalists and awardees were more likely to report their NIA projects as significantly different from their previous research (58% of finalists and 57% of awardees surveyed).

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[59] Caution should be used when interpreting this finding, as it is based on survey respondents who reported collecting preliminary data prior to submitting their applications. The actual percentage of applications that contained preliminary data was not known.

Exhibit 35. Applicant Survey Question: Was the work proposed in your NIA application a significant departure from your previous research?
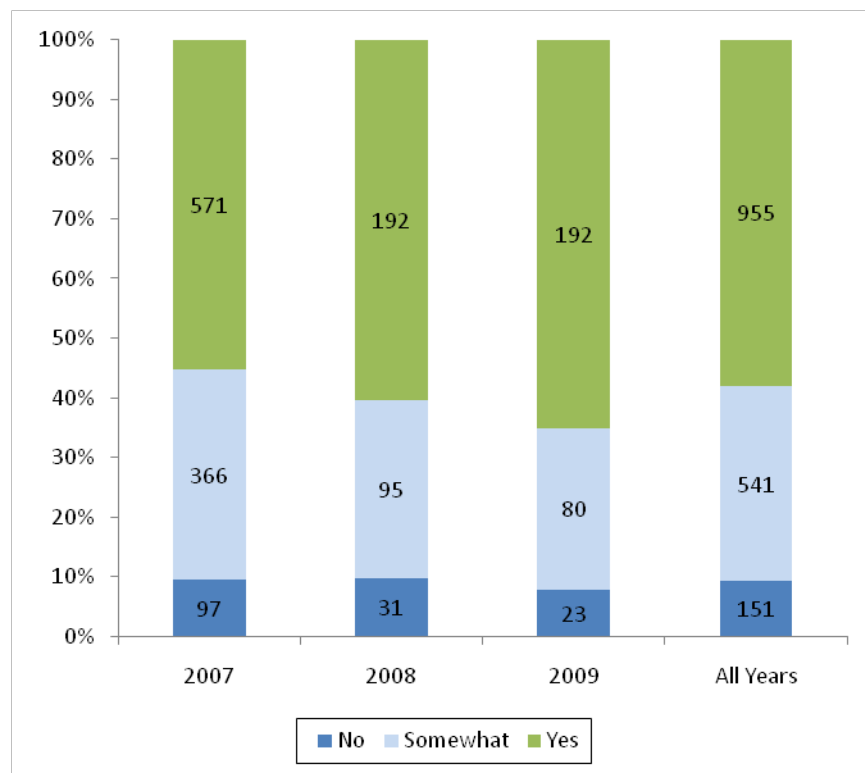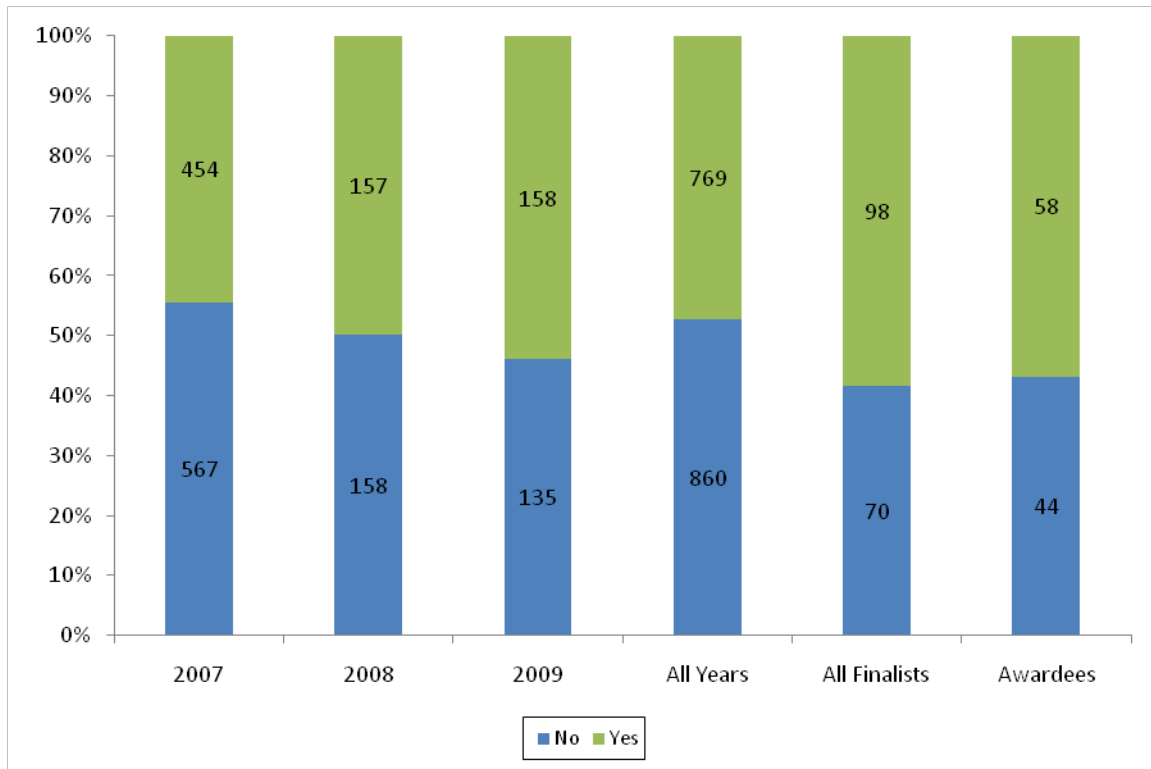

Source: NIA Applicant Survey.

Notes: The graph shows percentage distributions of applicant responses to a survey question. Number of respondents = 1,629.

Of the 321 survey respondents from FY 2009, 86 had also applied for an R01 in the same year. There were 74 who reported making substantial changes to their ideas or submitting a completely different idea for their NIA application (Exhibit 36). When asked how the applications differed, applicants typically stated that they submitted riskier elements of their idea to the NIA application and more conservative parts of the project for the R01.

Exhibit 36. Applicant Survey Question: How similar was the idea you submitted for the R01 compared to the one in your NIA application?

Response	Number of Responses (2009 only)
I submitted a completely different idea	54
I made substantial changes to my idea	20
I made minor changes to my idea	9
I submitted the same idea to both programs	3

Source: NIA Applicant Survey.

Notes: Question was asked only of 2009 applicants who also applied for a R01 the same year. Number of respondents = 86.

5.2.4   Feedback and Transparency

Of the repeat applicants who had reviewer comments on a previous NIA application, 31% reported they applied feedback on their most recent application, 33% reported they took feedback into consideration, and 35% reported they did not use feedback at all (Exhibit 37).

Exhibit 37. Applicant Survey Question: For your most recent NIA application, to what extent did you use the reviewer feedback provided on your previous application(s)?
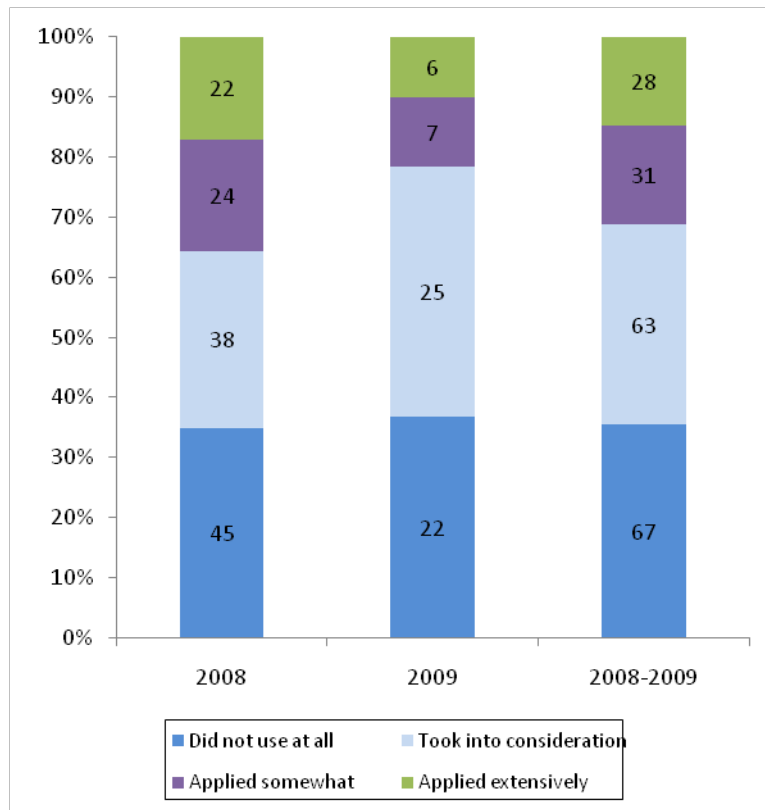
Source: NIA Applicant Survey.

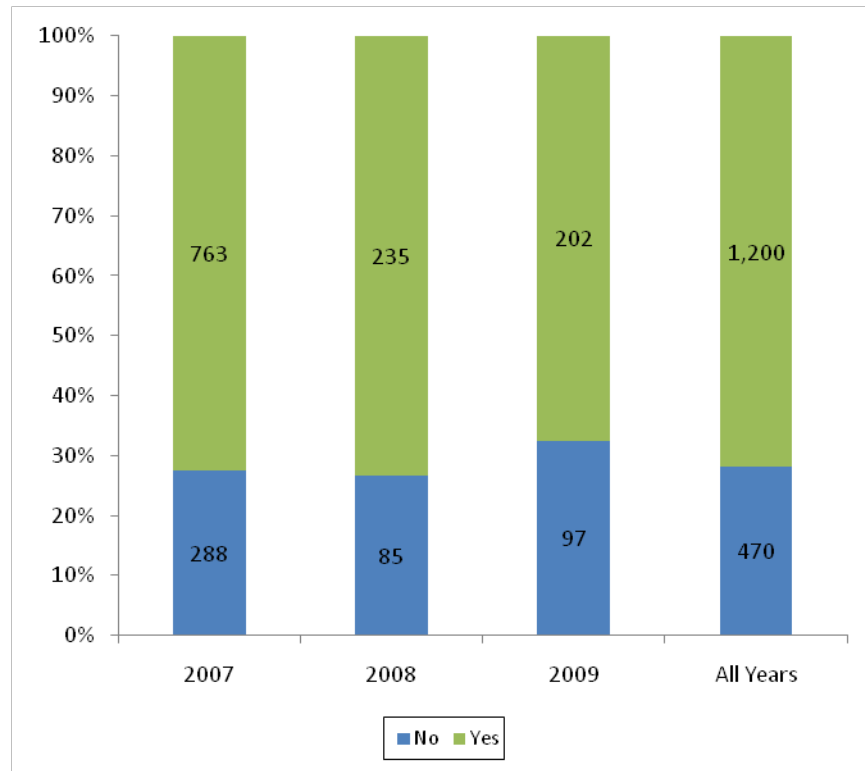Notes: The graph show percentage distributions of applicant responses to a survey question. This question was only asked of repeat applicants who first applied in FY 2007. Reviewers in 2008 were not able to leave feedback on the applications. Number of respondents = 189.

Although reviewers were able to leave short comments on the applications in FY 2009,[60] they were not able to leave feedback on applications in FY 2008. In FY 2007, reviewer comments were based on a set of sample comments from NIA program leadership that only addressed the importance of the scientific problem and the proposal's suitability for the NIA.[61] More than one-third (35%) of survey respondents who had received reviewer comments on their applications reported the feedback was unhelpful (Exhibit 38).

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[60]   Reviewer comments' were only visible to NIA program leadership and to finalists in FY 2009.

[61]   Refer to Section 6.3.4 for more details.

Exhibit 38. Applicant Survey Question: Were the reviewer comments on your application appropriate?
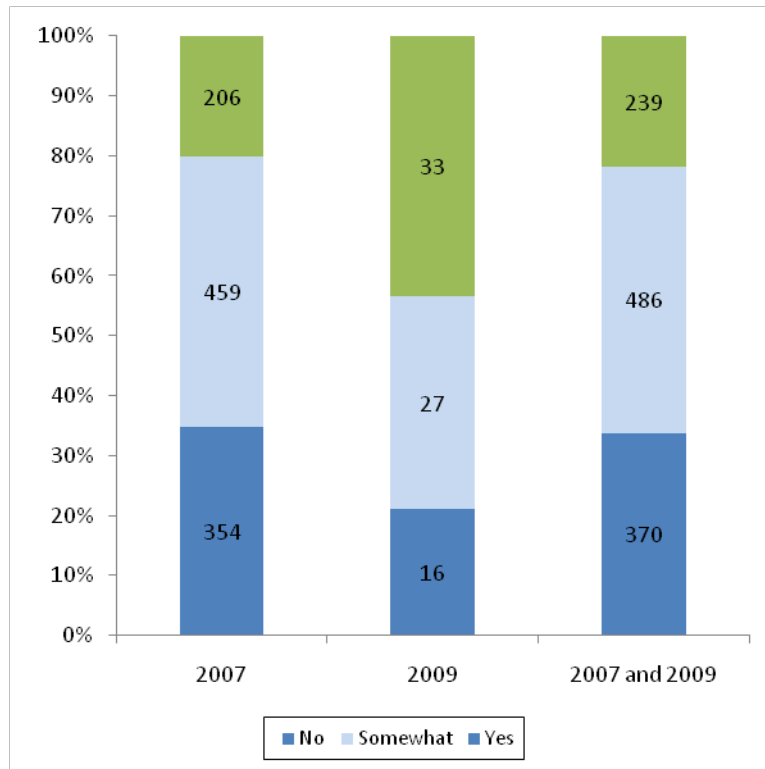
Source: NIA Applicant Survey.

Notes: The graph shows percentage distributions of applicant responses to a survey question. Reviewers in 2008 were not able to leave comments on the applications. Number of respondents = 1,095.

Examples of comments from applicants who did not receive feedback included:

"The review process is not appropriate for new investigators if NIA is designed to support new investigators. The PI got no reviewers' comments and did not know how the decision was made by each individual reviewer."

"I believe that the number of applications was so high that many applications were given only a cursory review, but to withhold that feedback, no matter how limited, from the applicants seems to result in a waste of their time as well as that of the reviewers."

"The reviewer feedback was very brief. I realize that there is no opportunity for a resubmission, but since this is for a new investigator, it is an opportunity for mentoring. Was the problem not important enough? Not ambitious enough? Not broad enough in scope?"

"I think reviewer comments or, at the very least, a numerical score for those applicants who don't make it past the initial review would be helpful. That way, it'd be easier to determine the likelihood of funding from the NIA as opposed to other innovation programs."

"My grant was not scored. It would have been beneficial, as a new investigator, to receive some feedback from the reviewers as to what the major flaws were in the proposal. This is my biggest complain with this process. Any feedback for new investigators is useful."

Other applicants recognized the difficulty of providing feedback in this situation and commented:

"The clearly huge number of applications required that the vast number be given very short and somewhat uninformative reviews."

"As a young investigator, it is truly helpful to have any reviewer comments on the proposal, even though it is rejected. I understand the overwhelming number of application for this particular grant. So, it may be practical to triage many of them first."

Applicants suggested that the reviewer feedback should be mandatory, and that comments should be detailed, with explicit comments for making future improvement to the proposals. Applicants also recommended incorporating a percentile score as part of the feedback, which could help explain how the application was received.

5.2.5   Program Management

Awardees had several thoughts on the NIA program management, and recommendations for improvements that they shared through the symposia focus groups, including:

- *Support for NIA awardees on how to enter the R01 system.* Several awardees stated that as new investigators, they would like to receive advice from program staff on how to write R01 applications, and to be informed about opportunities to serve on study sections so that they can learn about the R01 review process.
- *Better clarity that funds are allocated up front.* Several awardees said they had not known that the NIA funds are disbursed in one lump sum, and that had they known, they would have planned their budgets accordingly. These awardees acknowledged that this information was in the program documents, but that it was not highlighted. Awardees also suggested that this is an aspect of the award that may attract more applicants if it were emphasized.
- *Advice on how to find a mentor.* Some awardees requested advice from the NIA program on how to find a mentor, because as new investigators, they felt that they would benefit from formal advice.
- *Provide clarity on the purpose of the progress reports.* Many awardees stated that they had received neither instruction on what information should be contained in the progress reports, nor information on their purpose, which would have allowed them to target their writing more aptly.

5.3   Summary of Applicants' Perceptions

The analyses presented in this chapter address the applicants' perceptions of the NIA application and selection process using the survey of applicants and feedback from attendees of NDPA symposia focus groups.

Applicants seem to have expectations that NIA would provide career development support. According to the survey, the most common reason NIA applicants were attracted to the program was because it supports early-career investigators and nontraditional ideas, and applicants believed that as new investigators, they should receive targeted feedback on how to improve their proposals for future submission.

Applicants suggested the research categories may have been too broad, which prevented the reviewers from being accurately matched to the scientific area of the proposals. Over 80% of applicants reported they collected preliminary data before submitting an application and those who did not collect data were concerned that this negatively affected how their applications were reviewed.

More than half (53%) of survey respondents thought it was at least "somewhat likely" that their proposals could have been supported with other funding mechanisms, and 58% indicated that their NIA proposals did not represent a significant departure from their previous research. This finding demonstrates the breadth of the program design, as at least half of the applicant pool from the first three years captured individuals whose proposals were not significantly different from their previous research, and that the proposed idea was likely to have received traditional support.

Most survey respondents who also applied for an R01 in the same year reported submitting riskier elements of the idea, or a completely different idea for their NIA proposal. This finding indicates that applicants have recognized the purpose of the NIA is to serve as a complement to traditional funding mechanisms.

6.   Perceptions of External Reviewers

This chapter summarizes the approach and perceptions of the external reviewers with regard to the application review process.

6.1   Training

NIA reviewers were sent a training presentation that was further discussed in an orientation teleconference led by program leadership. During the teleconference, NIA staff outlined the objectives of the program, and in FY 2009, defined the purpose of the two review phases. When scoring the applications at a later time, reviewers were able to refer to these orientation slides to clarify review criteria.

Overall, 73 out of 96 reviewers interviewed (77%) agreed that the program goals were adequately defined and the review criteria were made explicit during the training session (Exhibit 39). However, 5 of 96 (5%) did not think that the program goals and terminology were made clear, while 8 of 96 (8%) relied on their previous experiences as reviewers when reviewing and scoring the NIA applications.

Exhibit 39. Reviewer Interview Question: During the training, were the program goals adequately defined and were the review criteria made explicit?
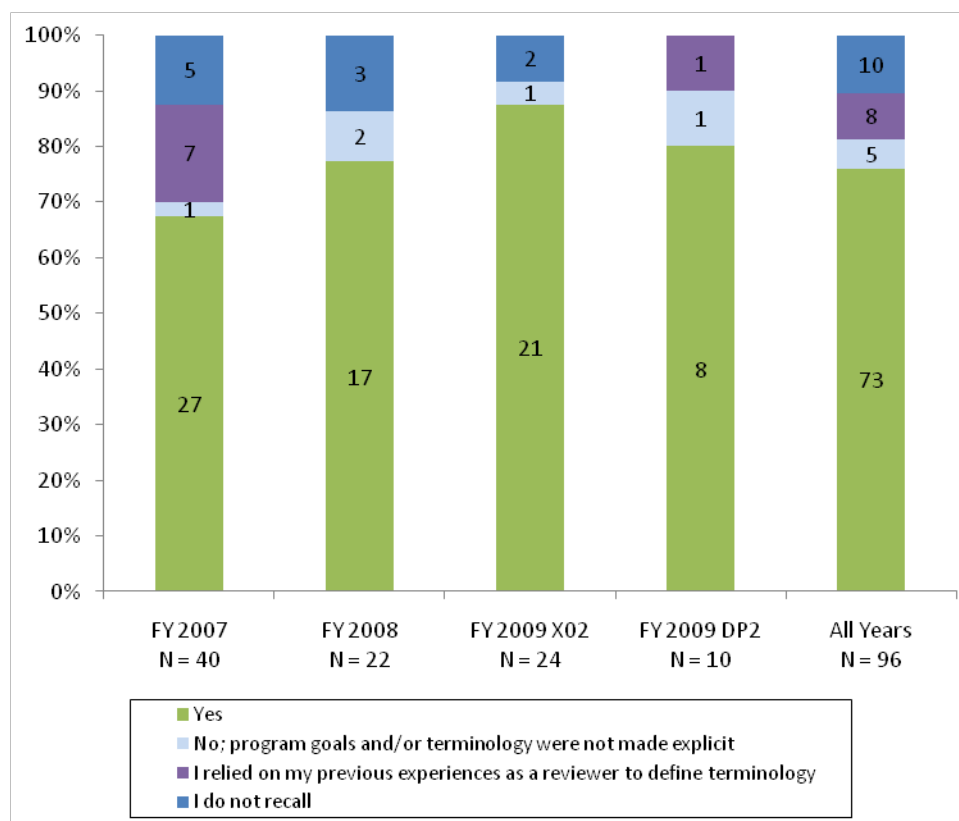
Source: NIA reviewer interviews.

Note: The graph shows percentage distributions of reviewers' responses to an interview question.

Examples of comments from reviewers who did not think the program goals were well defined after orientation included:

> *"I think it would have been better if they had made clearer the distinction between what should be funded by NIA and the difference between that and what is funded by R01s. Some of the applicants say that their idea wouldn't be R01-funded, and in many cases they're right, but some of them are right on the edge. I think a little more specificity at the beginning for everybody would help sort some of those out faster."*

> *Another reviewer felt that the review lack of clarity was due to the nature of innovation and creativity itself: "Review criteria weren't made explicit. But there couldn't have been anything (done) to make it clearer."*

Other reviewers thought that the goals and criteria were adequately defined, but they had trouble interpreting the program's terminology:

> *"Yes they explained it, although I don't fundamentally understand what that means."*

> *"I find it hard to read a proposal and get a sense if it is innovative or not... I relied on my experience… [and] I think the review criteria were made explicit."*

> *"Yes, review criteria [were defined] as well as they could be, I have my own issues with identifying innovation, by definition it should be something not understood or appreciated. It is a circular sort of concept."*

Based on feedback received during the reviewer interviews, it appears that reviewers may have understood the criteria, but had difficulty interpreting them, specifically when judging the innovativeness of the proposal.[62]

6.2   Scoring Applications

6.2.1   Assigning the Top 4 Designation

In addition to giving scores, external reviewers were instructed to designate the "Top 4" applications out of the pool of applications they reviewed. Reviewers from FY 2009 recalled that each application was unique, and many felt that reading the full group of applications first helped them to calibrate before beginning to assign scores. Assigning the Top 4 was mostly an intuitive assessment of the best applications, but some reviewers primarily based the Top 4 designation on specific criteria, such as the potential of the PI, degree of innovation, feasibility of the project, and potential impact on science (Exhibit 40).

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[62] Analyses found in Section 7.5.3 corroborate this finding because innovativeness was the review criterion for which there was the lowest agreement among the scores of reviewers.

Exhibit 40. Reviewer Interview Question:
How did you assign the Top 4 designation?
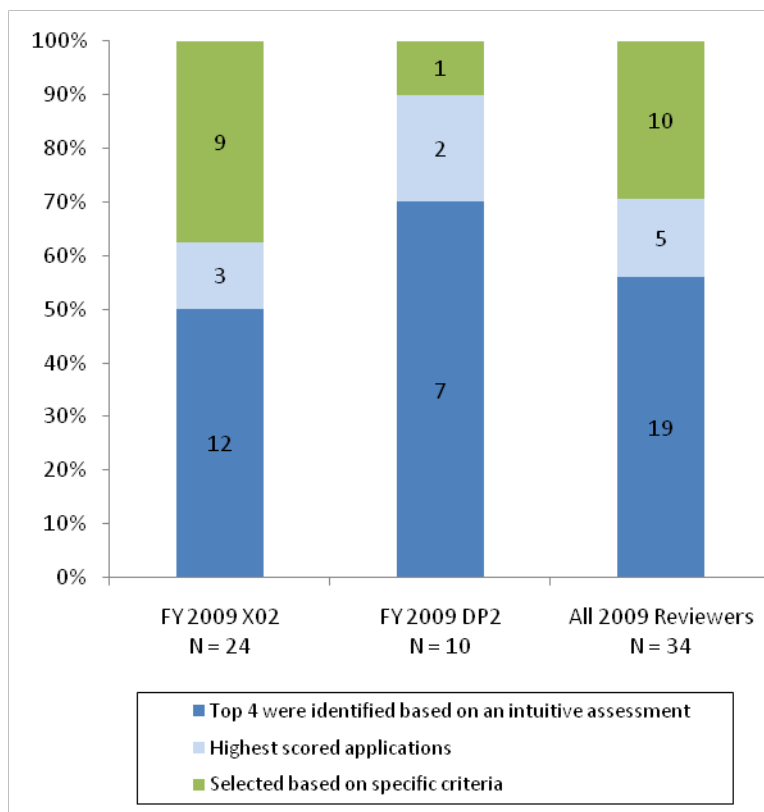
Source: NIA reviewer interviews.

Notes: The graph shows percentage distributions of reviewers' responses to an interview question. The wording of the question was slightly different in FY 2007–2008 and the responses are therefore not displayed here.

When asked how they picked the Top 4 applications, reviewers offered:

"I picked the ones that I thought were most interesting and what they were looking for."

"I assigned top 4 based on what was a great idea. [Then,] they had to have some level of proof that they were a successful person, whether they were a post-doc or grad student. Then I was looking for feasibility. Ideas, quality of the person, and then feasibility."

While reviewers agreed that the "Top 4" applications had received the highest scores, 10 out of 34 reviewers used a specific criterion to assign the distinction and another 19 reported using their intuition.

Not only did the reviewers have different approaches to assigning the Top 4 designation, reviewers did not all receive the same number of applications.[63] The varying number of applications received may

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[63] STPI did not receive information on how many applications each reviewer received. However, dividing the number of applicants in a given year by the number of reviewers in that same area yielded a range of fractions (from a low of 1.2 to a high of 12.31 applications to reviewers).

have affected reviewers' strategies for picking the best applications and rendered the process more difficult for some reviewers. Of the 62 reviewers interviewed from the first two years of the program, 22 (34%) reported not having difficulty when identifying the Top 4 applications, while 23 reviewers (37%) found the task to be difficult because there were fewer or more than four applications that deserved the distinction (Exhibit 41). Reviewers suggested that the program use a priority list or allow reviewers the flexibility to designate fewer or more than four applications. They thought these would be appropriate alternatives to most efficiently identify the top applications.

Exhibit 41. Reviewer Interview Question:
How difficult was it to choose the Top 4 applications?
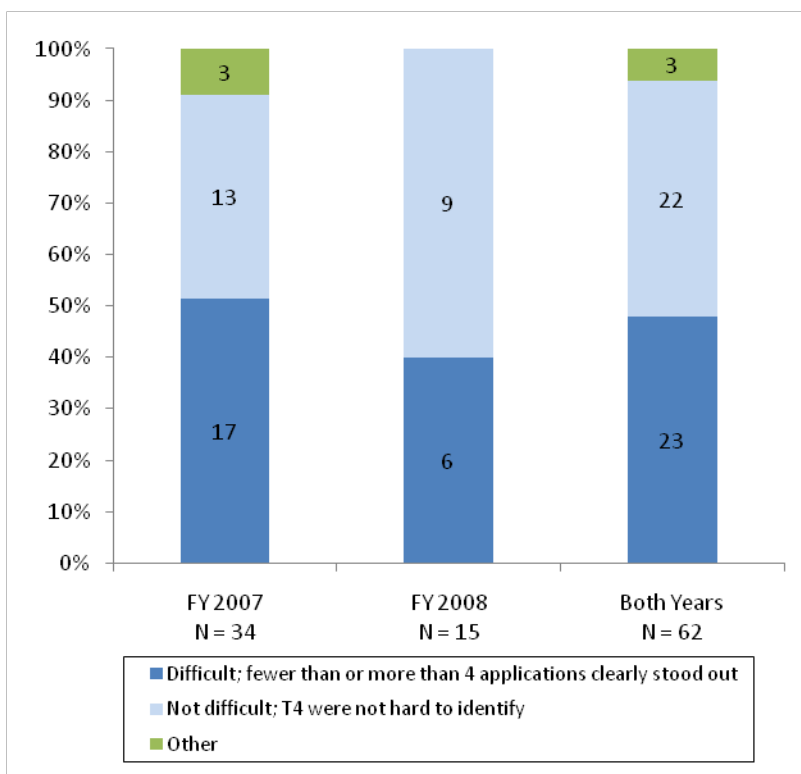
Source: NIA reviewer interviews.

Notes: The graph shows percentage distributions of reviewers' responses to an interview question. This question was only asked of reviewers who participated in FY 2007–2008. The wording of the question in FY 2009 was slightly altered and the responses are therefore not shown in this chart. The three "Other" responses noted that there were too many applications to spend time carefully reviewing applications (2 respondents), and that it was too difficult to take multi-dimensional applications and rate them on a single scale (1 respondent).

6.2.2 Review Criteria

Reviewers assigned scores to three criteria: applicant (PI) qualifications, importance of scientific problem, and innovativeness of the proposed research. They also gave an overall score and

distinguished the Top 4 applications from the group of applications they reviewed. Across all three years, when they did not consider two or more of the criteria equally important, reviewers weighed the innovation criterion most heavily when assigning overall scores (Exhibit 42). Although innovation was the criterion considered to be most important, the significance of the scientific problem and creativity of the approach were sometimes how reviewers distinguished the proposals from one another. Reviewers indicated this was an important step since the investigators were all at early stages in their careers.

Exhibit 42. Reviewer Interview Question: Which of the review criteria was most important to you in your assessment of the applications?
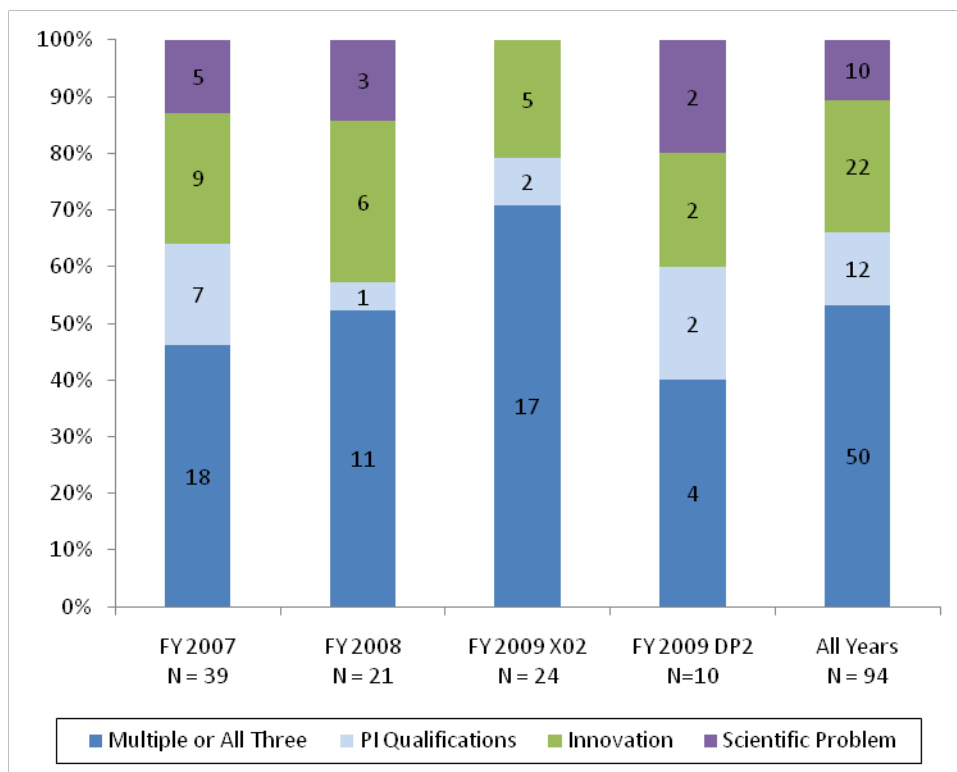
Source: NIA reviewer interviews.

Note: The graph shows percentage distributions of reviewers' responses to an interview question.

Reviewers offered several definitions for innovation which ranged from "a conceptual advancement in a field" to "something you know when you see." When asked which criterion they considered most important reviewers commented:

> "I weighed innovation the most because it's the Innovator Award…This is a special award, and these are junior people who don't have a strong track record but they had a 'wow' idea. I had a person here who came to my lab as a post-doc and is now a professor, and he got one of these with just an innovative idea."

> "What was proposed was most important—if it was imaginative or different from what someone would normally have funded."

While reviewers believed that the innovativeness of the proposal was one of the more important review criteria, there was no consensus on how innovation is defined or recognized.

6.2.3 Applications with Preliminary Data

Although preliminary data was not a required part of the application, 51 out of 75 (69%) interviewed reviewers stated that its presence had a positive effect on their review (Exhibit 43). Reviewers used preliminary data when included, and despite the lack of requirement, they reported that applications with data usually fared better when they were scoring.[64]

Exhibit 43. Reviewer Interview Question: How did the presence or absence of preliminary data affect your review?
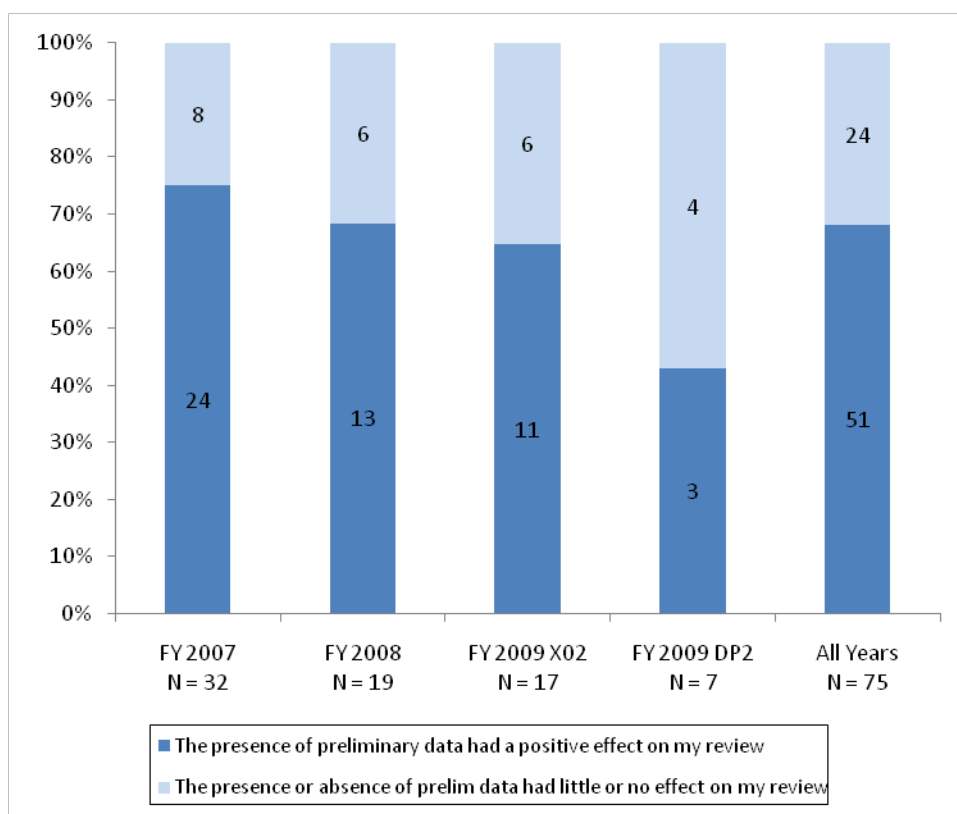
Source: NIA reviewer interviews.

Note: The graph shows percentage distributions of reviewers' responses to an interview question.

Selected reviewer quotes provide additional insights:

"At least two-thirds of them contained preliminary data. I'm going to guiltily say it does affect my review. We're always told that it's not necessary and not to penalize them for not having it. If

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[64] We found the odds of applicants advancing as finalists or awardees did not increase for respondents who reported collecting preliminary data versus those who did not. Refer to Section 5.2.2 for more details.

they didn't have preliminary data, I didn't penalize them but those that did have preliminary data did get a higher score. Often times, you're excited by preliminary data."

"Too many include preliminary data, then they start becoming like R01s and we already have an adequate R01 program. I don't want to see preliminary data. It is not the point of this project. I may have used it in areas where I [did] not feel confident."

It was reported that preliminary data helped reviewers "*paint the picture*" and interpret the feasibility of the proposal, especially when the subject area deviated from their expertise. Reviewers recommended submission of preliminary data either be prohibited or required to eliminate the selection bias that occurs when preliminary data are present.

6.2.4   Evaluating Applications Outside Their Scientific Expertise

Unlike the NDPA, the NIA sought to match reviewers to the research areas of the applicants. Nevertheless, the research area designations were broad and may have resulted in situations where the reviewers scored applications outside their areas of scientific expertise.[65] Across all years, 66 out of 89 (67%) reviewers interviewed reporting being "comfortable" evaluating applications outside of their area of expertise (Exhibit 44). During the interviews, reviewers reported using reference material or seeking help from a colleague when approaching applications in a scientific area of which they were not familiar. Reviewers also cited that they made judgments based on how well the grant applications were written, and that they approached applications outside their scientific expertise in the same way that they approached other applications.

Conversely, 23 out of 89 reviewers (26%) interviewed were "uncomfortable" (with approximately 10% stating they were "very uncomfortable") evaluating applications outside their area of expertise; a few stated they contacted program leadership to report their discomfort and some refused to review such applications. This finding provides a partial explanation for why some applications did not receive a full set of scores.[66]

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[65]   Section 5.2.1 indicates that 72% of NIA applicants found the research area designations to be sufficient for their needs.

[66]   Section 6.3.4 discusses the reasons and explanations for missing scores.

Exhibit 44. Reviewer Interview Question: Were you ever uncomfortable reviewing an application because you were unfamiliar with the subject area?
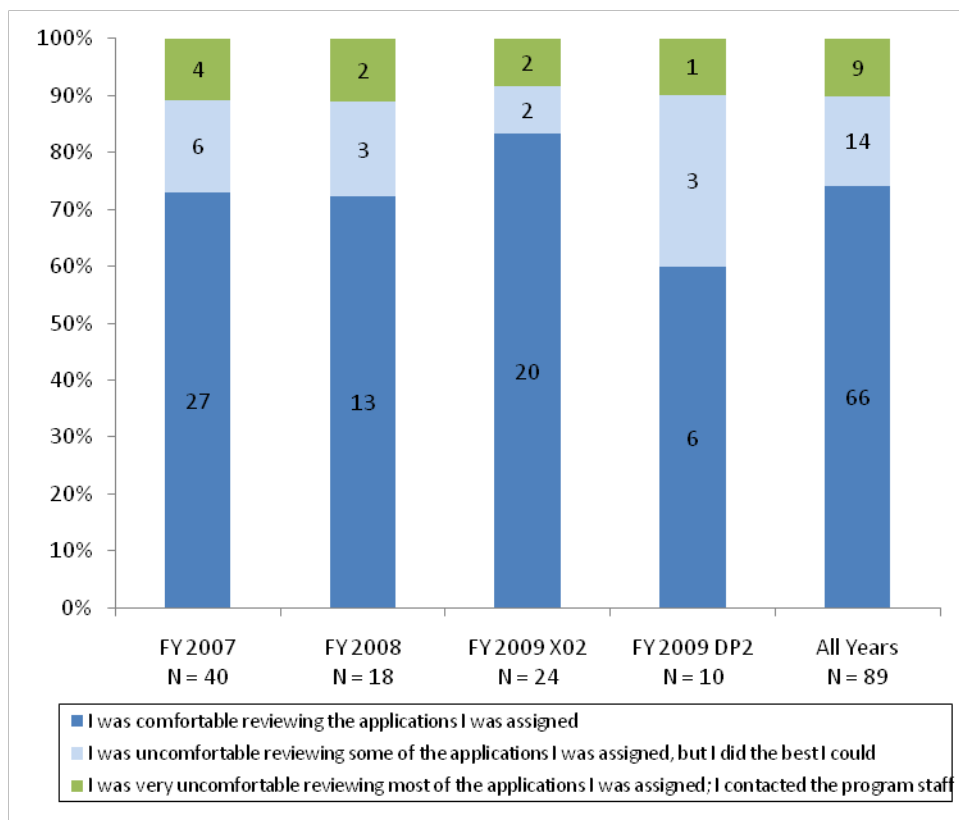
Source: NIA reviewer interviews.

Note: The graph shows percentage distributions of reviewers' responses to an interview question.

Reviewers who were comfortable reviewing applications outside their area of expertise stated that they depended on the applicant's grant to convince them of the feasibility and significance of the proposal, particularly since there was neither an interview nor study section. They commented:

"If a person demonstrates that they can explain something to me that goes a long way. That shows they know what they're talking about. The chance that you're going to have an expert sitting in the room who understands exactly what you're doing is rare. A lot of grant-writing is good writing skills, so if people write well, they're always ahead. The ones that are outside my expertise, it's important that they teach me what they're doing."

"If an applicant can make me excited about a project outside my area of expertise, then that is good."

"I think the fun of this review was that hardly any were in exactly my area. But in the essay format, applicants had a chance to develop their story in a narrative and less technical form, making it easier for the non-expert."

Reviewers interviewed from FY 2009 occasionally added that they were more at ease reviewing applications outside their specific area because they knew that the applications had been, or would be proceeding through a multi-phased review. Phase II (DP2) reviewers commented:

> "It wasn't just me, there were other people reviewing. When we had the conference call, I was impressed that despite the fact that we were reviewing outside our area, there was little conflict of opinion. That made me feel a little bit better."

> "Since they had already been through a first phase of review by the time they got to me, I didn't worry too much."

Reviewers who were uncomfortable with reviewing applications outside their expertise stated:

> "I might have sent an e-mail to the program staff or included it in my review. It just felt odd to review something about which I had absolutely no idea."

> "I was forced to review things way outside my area of expertise. I think it's a flaw, and I don't know how you get around that because there are so many applications and only so many reviewers. A lot of times, I felt uncomfortable because some applications were way outside my area and I didn't have the know-how to judge them."

6.3   Review Process

6.3.1   The FY 2009 Two-Phase Review Process

As explained earlier, a second phase of review was added in FY 2009.[67] Although reviewers from both phases participated in the conference call training session conducted by NIA program leadership, some interviewed reviewers gave contradictory descriptions of how the purpose of each phase of review was explained:

> "The first phase was a pre-screen to select the individuals that seemed to have the highest quality in terms of the program, and the second one was a refinement of that, particularly in innovation."

> "The first [round] was to determine degree of innovation and second round more thorough filter of technical review."

Based on feedback from the interviews, it is unclear if the goals and purpose of each phase were made clear to reviewers in FY 2009.

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[67]   Chapter 3 provides more detail about the changes to the FY 2009 review process.

6.3.2 Reviewer Feedback and Program Transparency

The majority of reviewers interviewed from FY 2009 were comfortable evaluating applications independently of the other reviewers (Exhibit 45), but 17 of 21 reviewers from FY 2009 Phase I (X02) reported that they would have liked feedback on how their scores compared. Reviewers complained that after dedicating an extensive amount of time to evaluating the applications, they neither heard back from NIA staff after submitting their scores nor understood how the final selection of awardees occurred. Although profiles of the awardees are published on the NIA website, 23 out of 34 reviewers interviewed (68%) from FY 2009 said they never learned who was awarded (Exhibit 46), and stated that they would have liked to have received notice from the program leadership.[68] Citing the opacity of the selection process and the low chance of applicant success, two reviewers stated that they felt compelled to discourage junior faculty in their institutions from applying to the NIA.

Reviewers felt invested in the applications they reviewed, especially their Top 4, and wanted to know how the applications ultimately fared in the selection process.

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[68] STPI is unaware of whether reviewers received a formal announcement of the awardees from the NIA program leadership.

Exhibit 45. Reviewer Interview Question: Were you comfortable reviewing the applications independently?
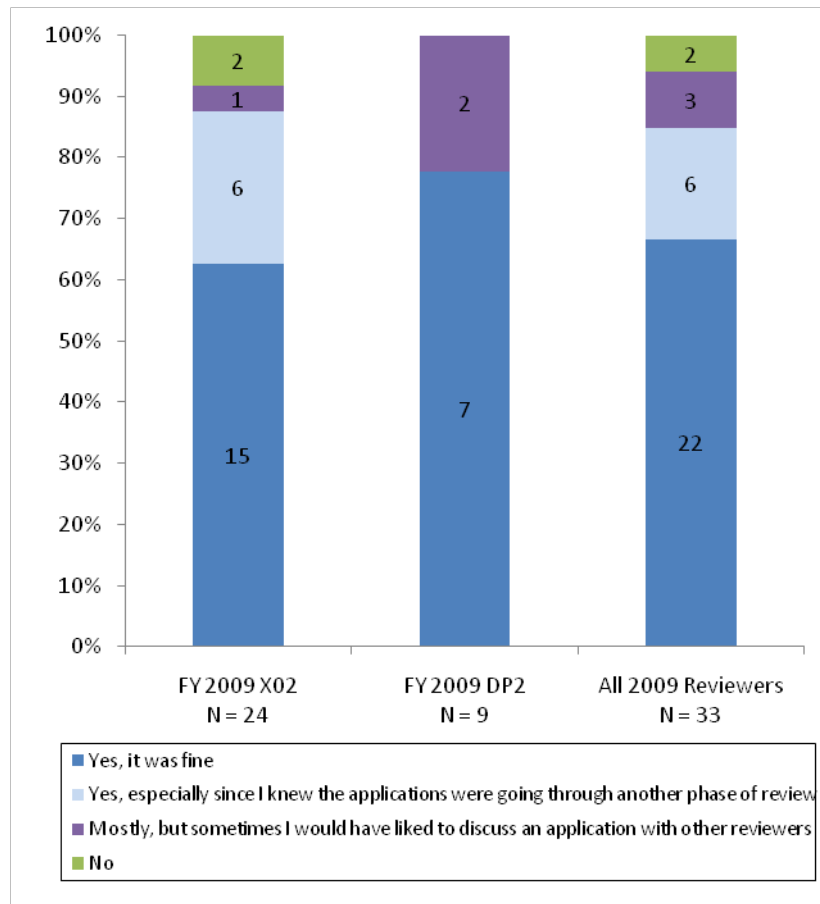
Source: NIA reviewer interviews.

Notes: The graph shows percentage distributions of reviewers' responses to an interview question. This question was asked only of reviewers from FY 2009.

Exhibit 46. Reviewer Interview Question:
Have you seen a list of the awardees?
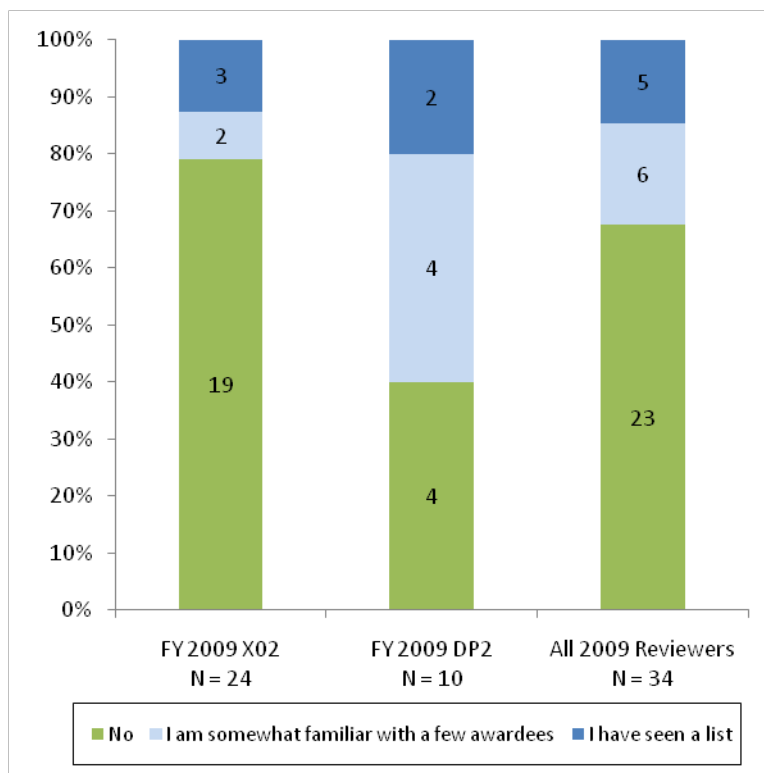
Source: NIA reviewer interviews.

Notes: The graph shows percentage distributions of reviewers' responses to an interview question. This question was asked only of reviewers from FY 2009.

6.3.3 NIA as a Distinct Funding Mechanism

Most reviewers who were interviewed characterized the pool of applications as being somewhat creative with a few proposals that were truly outside the realm of convention. A higher percentage of reviewers of Phase II (DP2) applications in FY 2009 found their applications to be innovative compared to reviewers in Phase I (X02) and other years (Exhibit 47). Only about 10% of the reviewers stated that the proposals were neither innovative nor outside the realm of convention.

Exhibit 47. Reviewer Interview Question: How would you characterize the applications in terms of creativity and innovation?
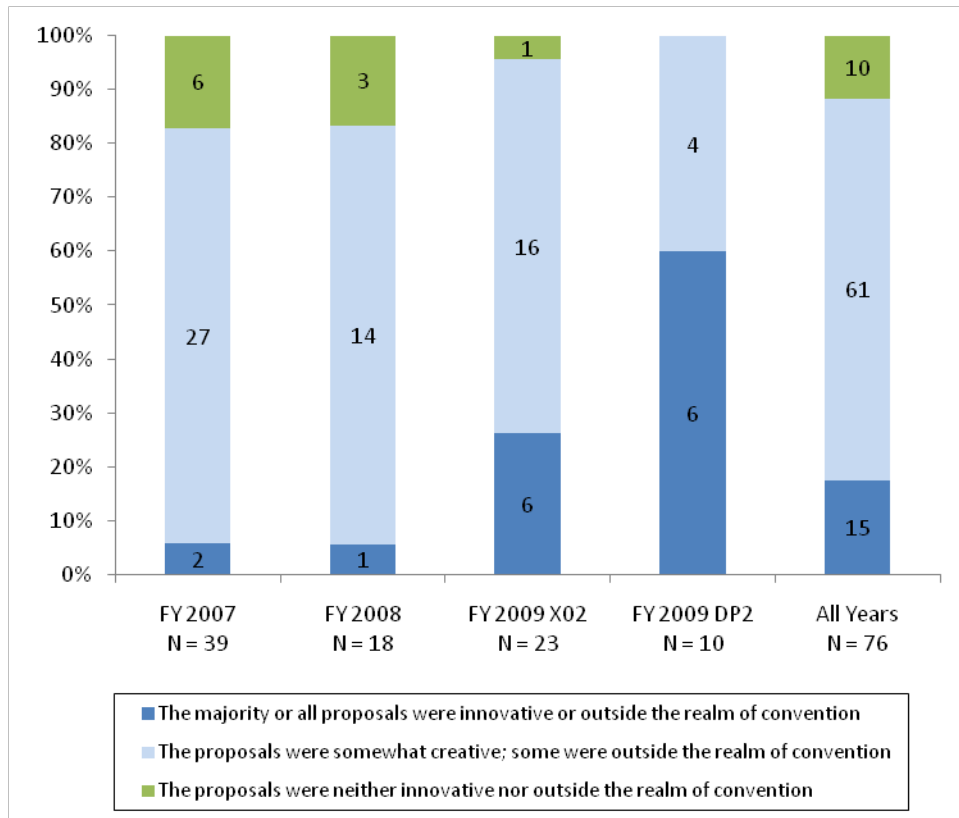
Source: NIA reviewer interviews.

Note: The graph shows percentage distributions of reviewers' responses to an interview question.

A majority of the reviewers interviewed believed that NIA is adding value to the NIH; 34% believe it is valued because it allows researchers to take risks and appreciates conceptual advancement, and 26% thinks it is a good concept but they cannot tell whether it is working (Exhibit 48).

Exhibit 48. Reviewer Interview Question: To what extent is NIA adding value to the NIH portfolio?
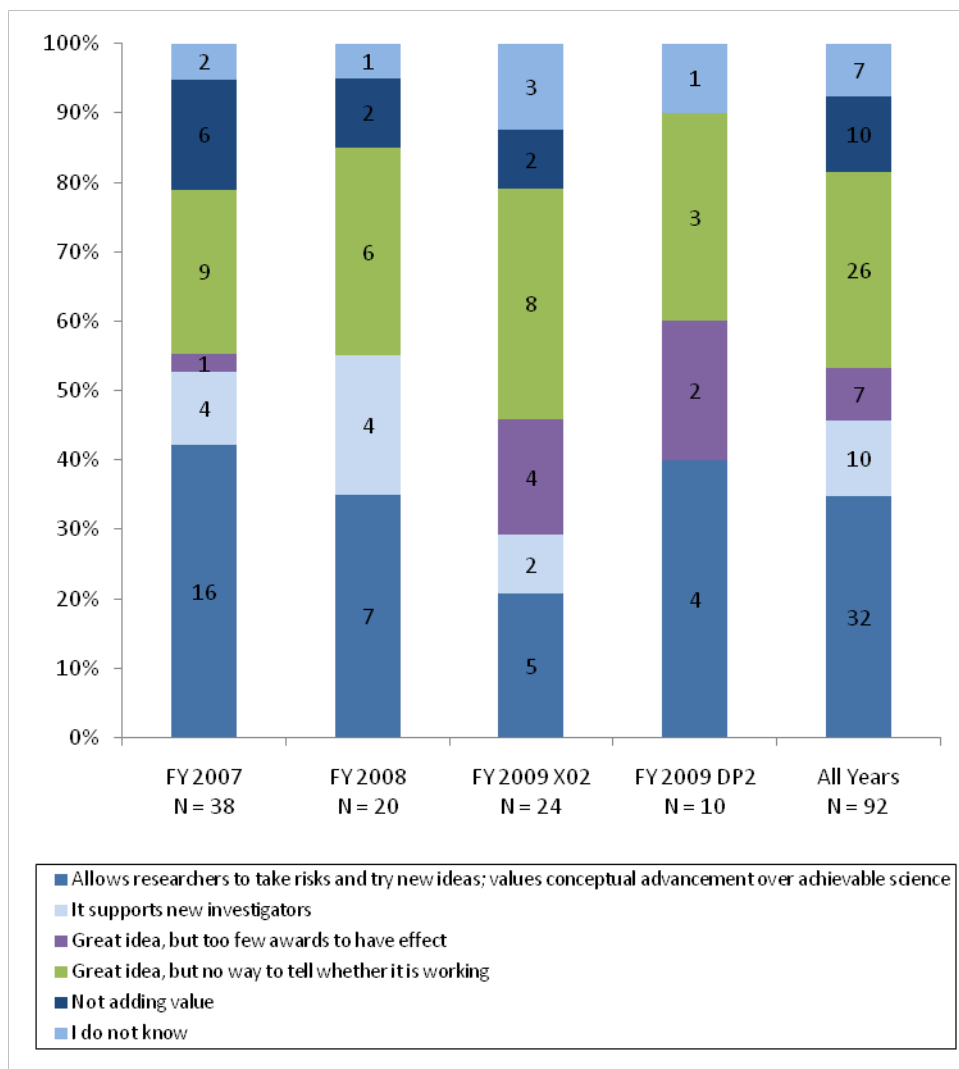
Source: NIA reviewer interviews.

Note: The graph shows percentage distributions of reviewers' responses to an interview question.

6.3.4 Technical Malfunctions and Problems with Reviewers' Comments

Throughout the first three years of the program, some applications did not receive a complete set of scores. In FY 2007, three applicants were missing scores from two reviewers. In FYs 2007–2008, ten finalists (three of whom were awardees) were missing scores from at least one reviewer. In FY 2009, 11 finalists were missing at least one reviewer's Phase I (X02) scores and five finalists were missing one reviewer's Phase II (DP2) scores.

Exhibit 49. Frequency of NIA Applications Missing Scores, FYs 2007–2009

Year	Number of Applications Missing Scores from at Least One Reviewer	Percentage of Applications Missing Scores from at Least One Reviewer
2007	214	9.9%
2008	14	2.4%
X02 2009	63	15.3%
DP2 2009	5	5.1%

Source: Application scores were provided by NIA program staff.

Note: The chart shows the number and percentage of applications in each year that were missing scores.

Scores were missing in some applications for several reasons. As mentioned in Section 6.2.4, a few reviewers revealed during interviews that they refused to score applications that fell too far outside of their research expertise.

Additionally, a few reviewers interviewed from FY 2009 reported technical problems when submitting comments and scores electronically. One reviewer admitted that once the issue was resolved, s/he did not try to re-enter scores for the applications with these technical problems. Thus, this issue may have resulted in the increased percentage of missing scores for FY 2009 X02 applications.

In addition to missing scores, FY 2007 experienced problems with reviewer comments. In the first year of the NIA, reviewers were instructed to provide open-ended feedback and NIA program leadership prepared a list of sample comments to serve as guidelines (Exhibit 50). Despite the provision of examples, few directions were given to reviewers on how to structure their feedback. Many comments were inappropriately worded or otherwise unsuitable for NIH to distribute to applicants. Consequently, NIA program leadership had to review individually and resubmit a total of 6,600 comments that year. This led to the elimination of reviewer feedback in FY 2008.[69] In FY 2009, reviewers in both phases were able to leave comments on applications, but only finalists received comments from DP2 reviewers; feedback on applications from X02 reviewers was only made available to NIA leadership and staff for internal use.

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[69] Interview with NIA program leadership, October 24, 2008.

**Exhibit 50. Selected Sample Comments provided by NIA Program Staff for
External Reviewers to Use When Reviewing Applications, FY 2007**

Type of statement	Sample comments provided by NIA Program Staff for External Reviewers to Use when Reviewing the Applications
Significant scientific problem, suitable for NIA mechanism	The proposed project is of significant scientific interest and addresses an important problem in biomedical/behavioral research.
Significant scientific problem, though not suitable for NIA mechanism	The proposed project is of scientific interest. Its overall significance, however, is somewhat less than that expected for a New Innovator Award, even though it will have a major impact on this important medical problem if it is successful.
	The proposed project, while of scientific interest, addresses a relatively narrow problem in biomedical/behavioral research. Thus its overall significance is less than that expected for a New Innovator Award.
	The proposed project is of scientific interest. This project is better suited to the traditional R01 grant mechanism.
	The proposed project, while of interest to the field, is not of the level of significance/importance expected for a New Innovator Award.
Problem is not of scientific significance, nor suitable for NIA mechanism	The proposed project will produce results that will be incremental but will not break new ground and will not have the level of impact expected for a New Innovator Award.
	The proposed project is of limited scope and not at the level of importance expected of a New Innovator Award.

Source: Application data was obtained from NIA program staff, and categorization of reviewer comments was performed by STPI.

6.3.5   Satisfaction with Review Process

Overall, 74 out of 93 reviewers interviewed (77%) enjoyed the review process and indicated they would participate again in the future (Exhibit 51). Reviewers often cited their desire to support innovation as the reason for their repeated involvement. Examples of responses from reviewers who would participate again in the future included:

"Yes, I like the innovative things and they keep you fresh."

"Sure, I am happy to do so and I refuse other requests to review from NIH, so I do this out of the goodness of my heart, to favor innovation."

"Yes, I think this is very important to science, so I would certainly consider my re-involvement."

"Sure, I want to help innovation in any way I can."

Exhibit 51. Reviewer Interview Question: Given your experience as a reviewer, would you be involved in the future?
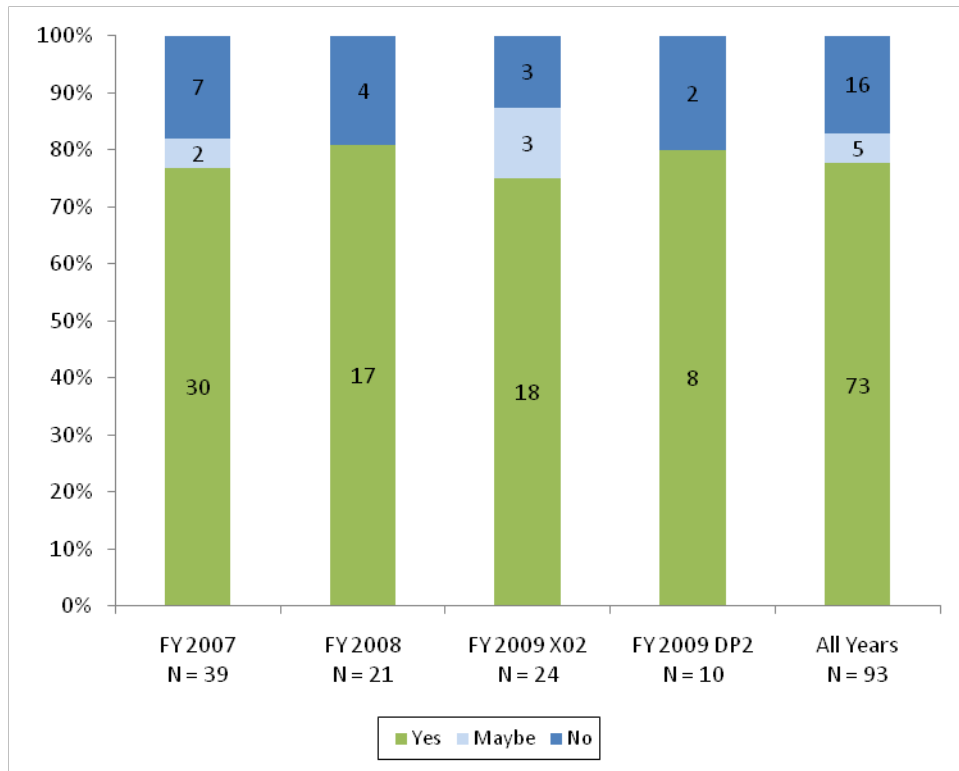
Source: NIA reviewer interviews.

Note: The graph shows percentage distributions of reviewers' responses to an interview question.

Several reviewers who were unsatisfied with the review process made comments on how it could be improved in a way that would encourage them to review again for NIA. These included:

- Facilitate a better match between the subject area of the applications and the research area of the reviewers
- Increase the overall transparency of the selection process and the contact between program staff and reviewers
- Include a screening round to confirm the applications' suitability for the NIA mechanism[70]
- Decrease the number of applications assigned to each reviewer
- Enable reviewers to discuss the applications with one another
- Increase the number of awards

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[70] This feedback was provided exclusively by reviewers who participated in FY 2007–2008. A second phase of review was added in FY 2009.

6.4   Summary of External Reviewers' Perceptions

This chapter presents information on the perceptions of reviewers regarding the NIA review process and program. Information was gathered through reviewer interviews.

Regarding program leadership's communication with reviewers:

- Reviewers may have understood the review criteria, and believed the program goals were adequately defined during the training session, but cited difficulty interpreting the "Innovativeness" criterion.
- In FY 2009, the purpose of each of the two review phases was not clear to reviewers, despite their participation in training with program leadership. More explicit instruction may be necessary for reviewers to accurately understand their purpose in each phase of the selection process.
- Although reviewers were mostly comfortable reviewing independently, reviewers would have enjoyed feedback on how their scores compared to those of other reviewers.

Regarding the scoring and review process:

- Reviewers varied in the ways they chose Top 4 applications; some relied on tangible criteria such as a PI's potential, the degree of innovation, feasibility, the potential impact, the highest scoring applications; others relied on intuition.
- Reviewers indicated that the Top 4 designation may not be the most efficient method of identifying the strongest applications, as often fewer or more than four applications deserved the distinction.
- When they did not consider two or more review criteria equally important, reviewers evaluated the innovativeness criterion most critically when determining overall score.
- Preliminary data had a positive effect on most reviewers (69%); thus, they suggested the supplement should either be required or not accepted.
- One third of reviewers were not comfortable evaluating applications outside their area of scientific expertise. This often led to missing scores, as reviewers declined to review applications when they felt they could not accurately evaluate the subject area.

Regarding reviewer perceptions of the NIA program:

- A majority of reviewers think NIA is adding value to the NIH, but believe it may be too early to assess the effects of the program.
- Most reviewers enjoyed the review process and would participate again.

7. Applications and Scoring Analyses

This chapter addresses the selection of NIA finalists and awardees, and investigates trends in application scores. Analyses presented herein examine whether the three review criteria (scientific problem, innovativeness, and investigator qualifications) were weighed equally by reviewers when assigning an overall score, as interviews suggested that reviewers may have weighted certain criteria more heavily than others. Further investigation tested how well the reviewers' scores correlated with one another, and whether there was a relationship between applicant characteristics and the scores received. Finally, this chapter examines the role that application scores played in the advancement of finalists and selection of awardees, to understand the program's processes for selecting awardees.

7.1 Average Scores by Criteria

As part of the review process, external reviewers were asked to score applications on each of the three review criteria using a scoring range of 1 to 5, as well as to give an Overall Score on the same five-point scale. Additionally, reviewers were instructed to designate exactly four applications with a Top 4 vote in order to distinguish the top choices in their pool of assigned applications.

The averages of the individual criterion scores and Overall Scores across FY 2007–2009 are shown in Exhibit 52. The average scores for each of the review criteria increased slightly each year; likewise, the average of all Overall Scores increased over the three years, ranging from 3.05 in FY 2007 to 3.31 in FY 2009 for the Phase I (X02) application round. The average Overall Score for the applicant pool was highest in the Phase II (DP2) round of FY 2009, at 3.48 (Exhibit 52). This is a predictable result since the FY 2009 DP2 applicants were selected from the highest-scoring Phase I (X02) applicants.

Exhibit 52. Average Criterion Score, FY 2007–2009
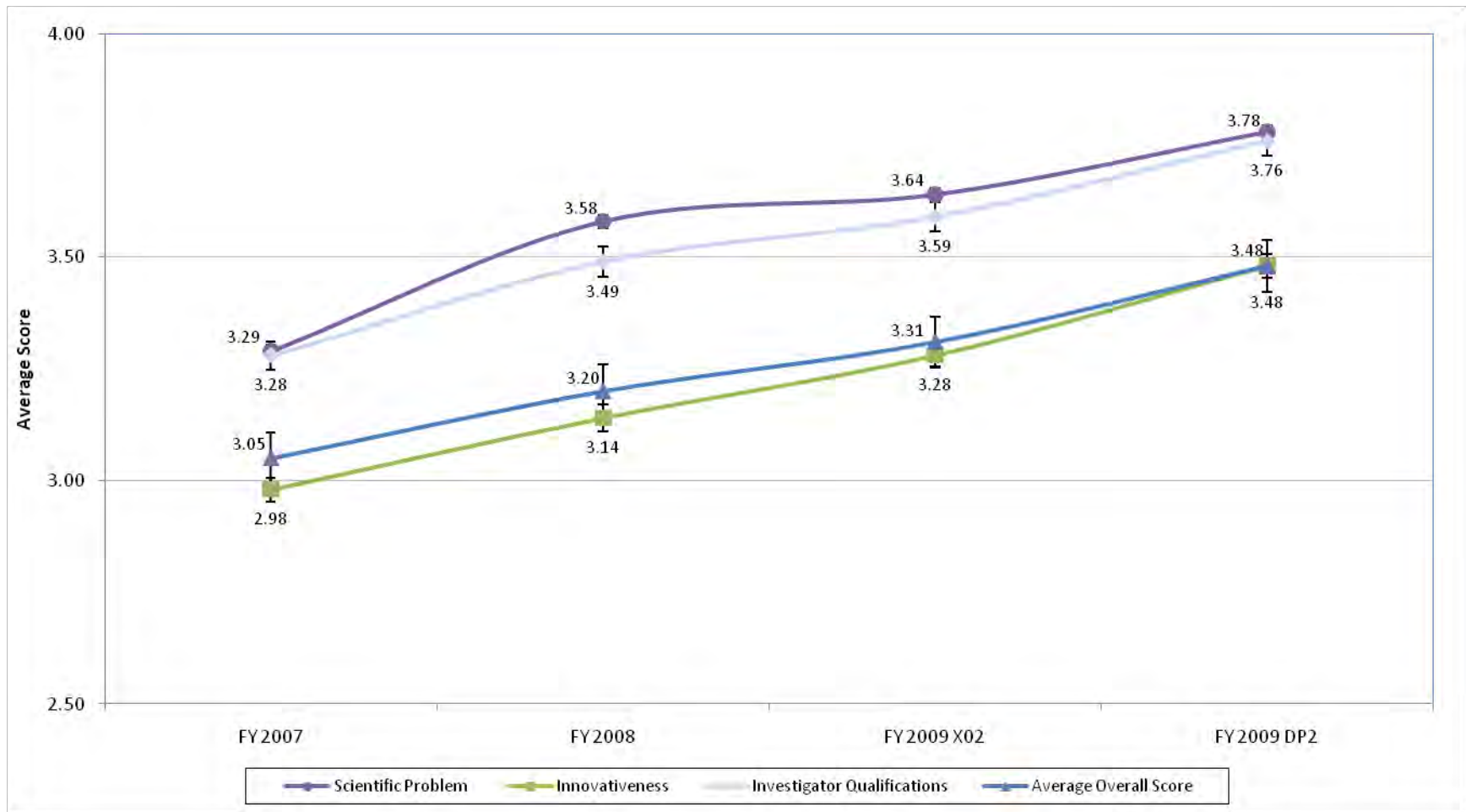
Source: Application scores were provided by NIA program staff.

Note: The line graph shows the averages of the individual criterion scores and Overall Scores, which increased across FY 2007–2009.

7.2 Correlation between Criterion Scores and Overall Score

In all three years, Overall Scores showed a strong positive correlation with each of the three individual criterion scores (Exhibit 53).[71] Thus, only Overall Scores were used in subsequent scoring analyses.

We note that although all individual criterion scores showed a positive correlation with the Overall Score, the "Innovativeness" criterion score showed the highest positive correlation with Overall Score. This finding is consistent with what was heard during interviews with reviewers. When reviewers did not weigh the three criteria equally, they most frequently reported considering the innovativeness of a proposal as most important when assigning Overall Scores.[72]

Exhibit 53. Relationship between Overall Scores and Each Criterion Score, FY 2007–2009

Correlation Coefficients of Overall Scores Versus:	FY 2007	FY 2008	FY 2009 X02	FY 2009 DP2
Scientific Problem	0.799	0.718	0.729	0.714
Innovativeness	0.858	0.857	0.823	0.816
Investigator Qualifications	0.785	0.788	0.768	0.669

Source: Application scores were provided by NIA program staff.

Notes: Spearman's correlation coefficient is a number between –1 and 1, where –1 indicates a perfect negative relationship, 1 indicates a perfect positive relationship, and 0 implies no relationship. Correlations like those seen here indicate a positive, monotonic relationship between the criterion scores and the Overall Scores; thus, high Overall Scores are associated with high criterion scores, and Overall Scores are expected to be low when the criterion scores are low. The scores from a total of 296 applications were not included in the calculation because scores from one or more reviewers were missing.

7.3 Score Distributions

An application typically received an Overall Score from each of its three reviewers,[73] and NIA program leadership used an average of the three Overall Scores, hereafter referred to as Average Overall Scores (AOS), to rank the applications for finalist advancement.[74] Distributions of all the Overall Scores and the Average Overall Scores, across the first three years of NIA are reflected in Exhibits 54 and 55. The Overall Scores for all applicants, as well as the Average Overall Scores, appear unimodal and symmetric for FY 2007, FY 2008, and FY 2009 Phase I (X02) (Exhibit 54). In all three years, applicants who advanced as finalists earned Average Overall Scores of greater than 3 (Exhibit 55).

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[71] When using a two-tailed test for calculating the significance of a Spearman Correlation Coefficient, if the sample size is n>30, any coefficient greater than .0478 will have a p<.01, and can be concluded to have a true correlation coefficient significantly different than zero.

[72] See Section 6.2.2 for details.

[73] Occasionally, applications did not receive a full set of scores. Details on the percentage of applications missing scores can be found in Section 6.3.4.

[74] Details on the selection process for finalist advancement are in Section 3.6.

Exhibit 54. Distribution of Overall Scores for Applicants, Finalists, and Awardees, FY 2007–2009
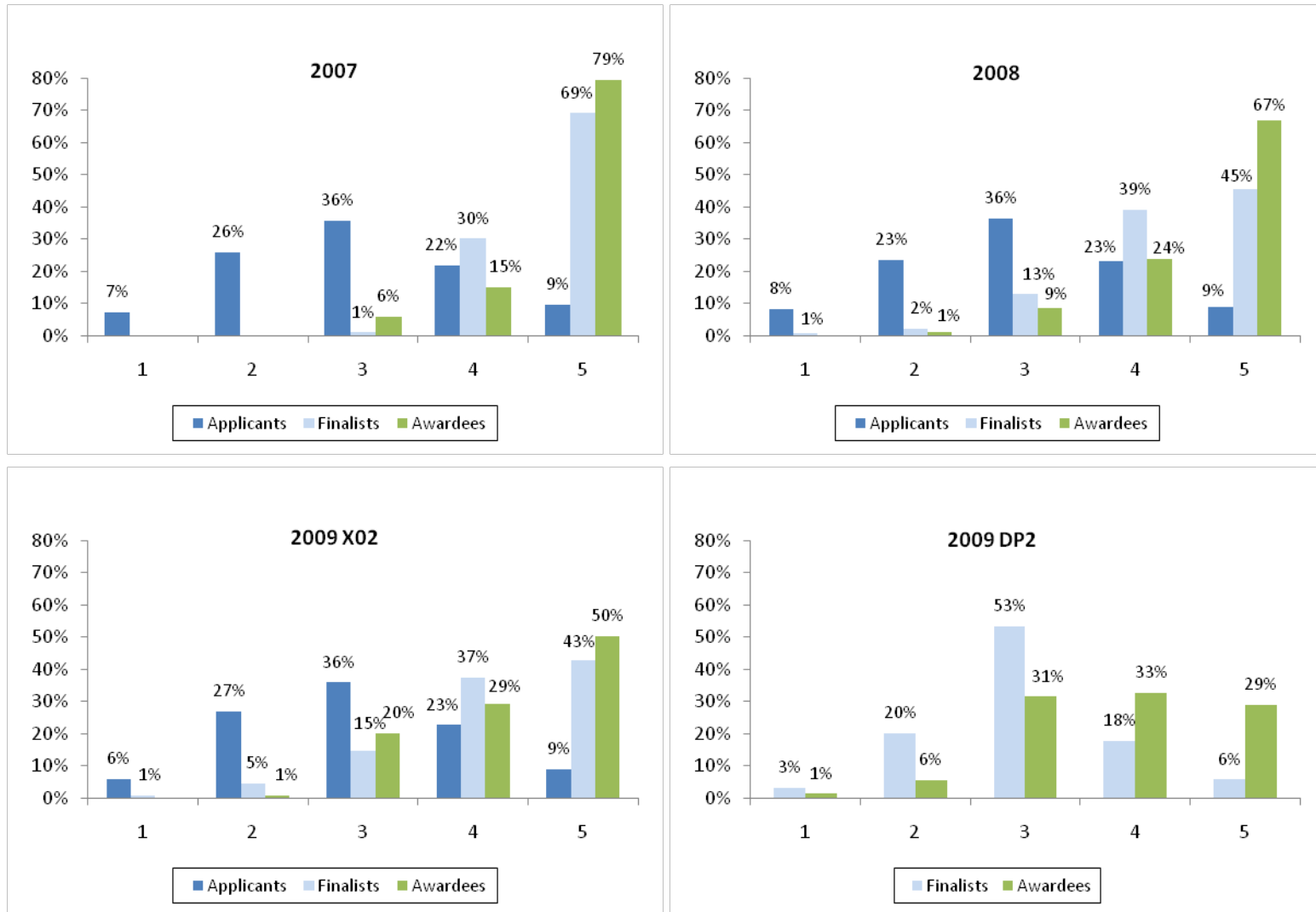
Source: Application scores were provided by NIA program staff.

Note: These charts show the distribution of the Overall Scores each application received from its reviewers.

Exhibit 55. Average Distribution of Overall Scores for Applicants, Finalists, and Awardees, FY 2007–2009
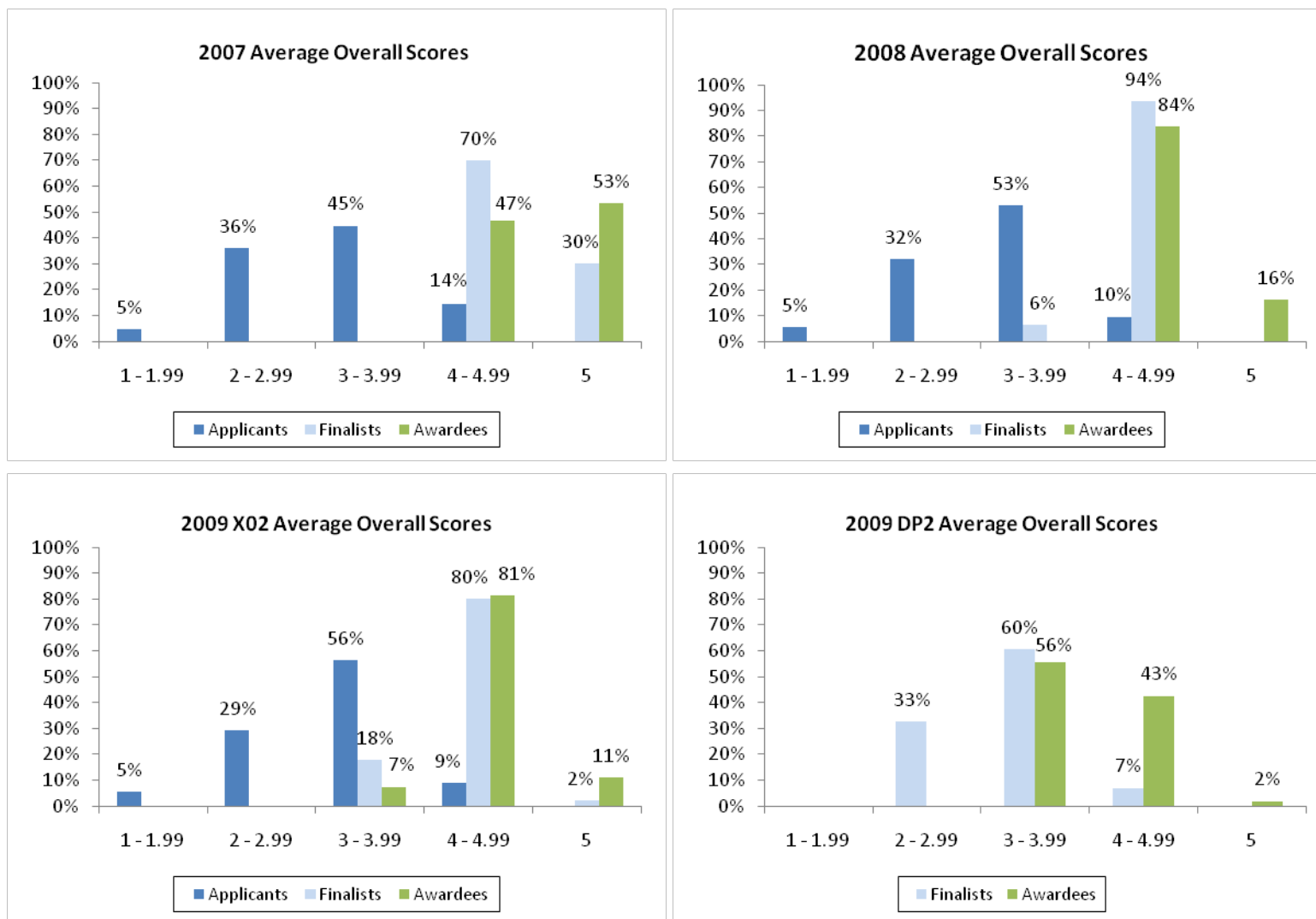
2007 Average Overall Scores

2008 Average Overall Scores

2009 X02 Average Overall Scores

2009 DP2 Average Overall Scores

Source: Application scores were provided by NIA program staff.

Note: These charts show the distribution of the Average Overall Scores.

Although the scores for applicants selected as finalists in FY 2009 Phase I (X02) were at the highest end of the unimodal and symmetric set, when the same applications were scored again in Phase II (DP2) by a different set of reviewers, the Overall Scores were redistributed to again resemble a unimodal and symmetric data set. This redistribution of Overall Scores into a unimodal and symmetric distribution during Phase II (DP2) is likely due to the inter-pool comparison of finalist applications by external reviewers. In other words, as the quality of applications in the pool was elevated, reviewers recalibrated their scores and marked down certain finalists who were strong relative to the entire applicant pool in Phase I (X02), but were less competitive when compared to the entire finalist pool (Phase II (DP2)). This finding affirms what was heard during reviewer interviews, as reviewers from FY 2009 frequently reported reading all the applications first to calibrate their pool before assigning scores.

7.4   Scores vs. Demographics

7.4.1   Scores by Gender

Male applicants received higher Average Overall Scores (Exhibit 56) and more Top 4 votes per applicant (data not shown) than females in FY 2007, FY 2008, and both phases of FY 2009, but these differences were only statistically significant in FY 2007.[75] Male applicants were also more senior in all three years but further analyses showed that there was no correlation between the Average Overall Score and the number of years since the applicant's last doctoral degree (data not shown).

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[75]   Welch t-test, p = 0.0002 for Average Overall Score; Permutation t-test, p = 0.0002 for Top 4 votes per applicant.

Exhibit 56. Average Overall Score by Gender, FY 2007–2009
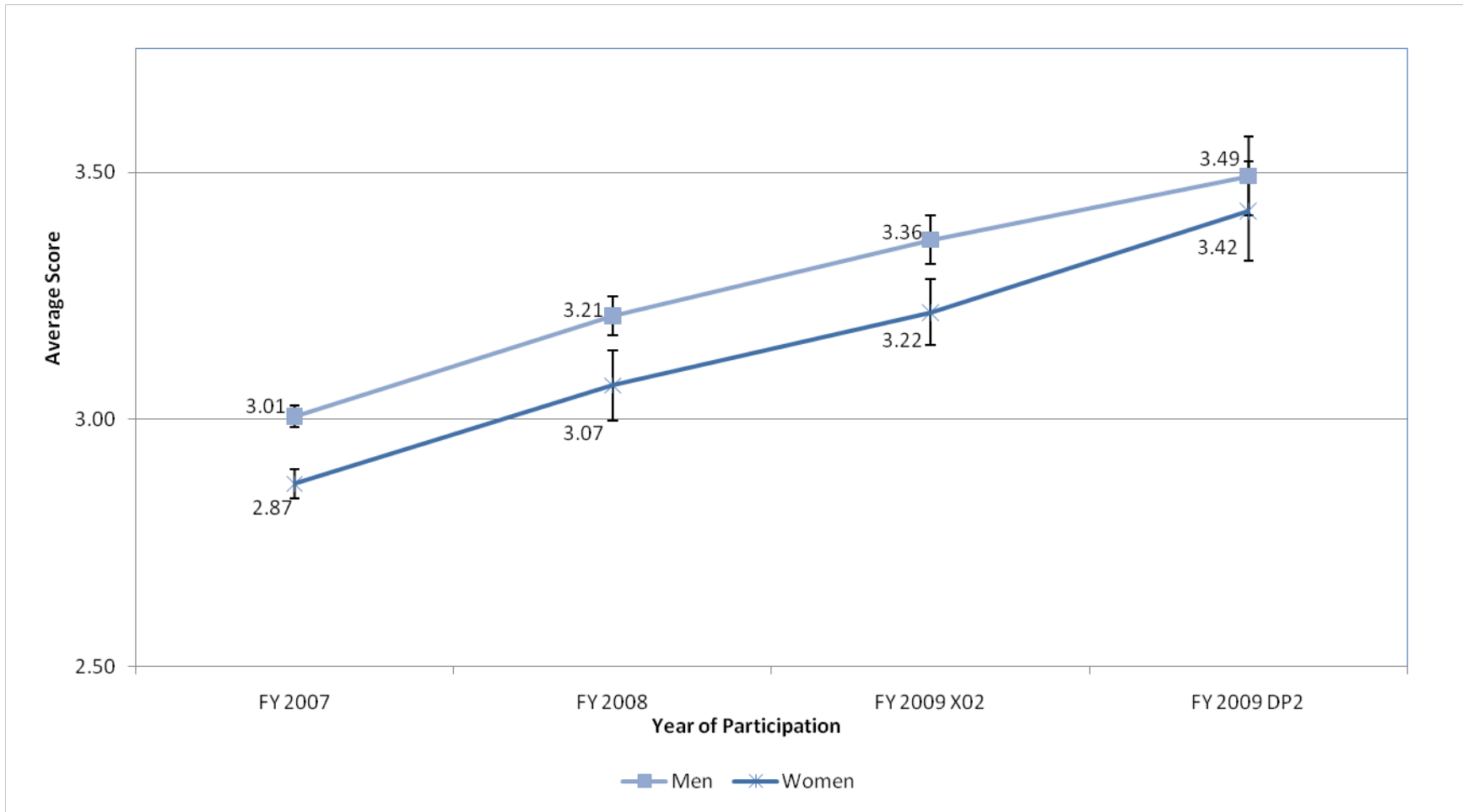
Source: Application scores and applicant gender data were provided by NIA program staff.

Notes: The line graph reports the Average Overall Score by gender, which increased across FY 2007–2009. Men had higher overall scores than women in FY 2007, FY 2008, and both phases of FY 2009. However, there were only significant differences between male and female applicants in 2007.

7.4.2   Scores by Research Area

In FY 2007, applications in the Behavioral and Social Sciences research area received significantly lower Average Overall Scores than applicants in other areas.[76] In other years, no significant differences were observed between research areas. The mean of the Average Overall Scores by research area is shown in Exhibit 57.

Exhibit 57. Average Overall Scores by Research Area, FY 2007–2009

2007			2008			X02 2009		
Research Area	**Mean Score**	**SE**	**Research Area**	**Mean Score**	**SE**	**Research Area**	**Mean Score**	**SE**
Behavioral and Social Sciences	2.87	0.04	Behavioral and Social Sciences	2.82	0.12	Behavioral and Social Sciences	3.31	0.11
Cellular Biology	3.17	0.04	Chemical Biology	3.14	0.08	Chemical Biology	3.52	0.12
Chemical Biology	3.02	0.05	Clinical and Translational Research	3.28	0.06	Clinical and Translational Research	3.37	0.08
Clinical and Translational Research	3.05	0.03	Epidemiology	2.94	0.13	Epidemiology	3.67	0.21
Epidemiology	2.93	0.08	Immunology	3.34	0.10	Immunology	3.31	0.13
Instrumentation and Engineering	3.14	0.05	Instrumentation and Engineering	3.16	0.09	Instrumentation and Engineering	3.31	0.09
Molecular Biology	3.11	0.05	Molecular and Cellular Biology	3.21	0.06	Molecular and Cellular Biology	3.11	0.07
Pathogenesis	3.13	0.04	Neuroscience	3.25	0.08	Neuroscience	3.40	0.10
Physiology and Integrative Systems	2.97	0.04	Physiology and Integrative Systems	3.39	0.10	Physiology and Integrative Systems	3.32	0.15
Quantitative and Computational Biology	3.22	0.06	Quantitative and Computational Biology	3.21	0.11	Quantitative and Computational Biology	3.46	0.13
All	3.06	0.01	All	3.20	0.03	All	3.31	0.03

Source: Application scores were provided by NIA program staff.

Note: FY 2007 was the only year in which there were significant differences between application scores.

7.5   Inter-rater Reliability

Analyses of inter-rater reliability were conducted to assess the degree of reviewer agreement when scoring applications. The analyses in this section examine whether agreement among reviewers varied across different award stages (applicant, finalist, and awardee), research areas, and review criteria. It

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[76]   Permutation t-test, p = 0.00001.

should be noted that the presentation of agreement measures in this report does not imply that an assessment was more robust if reviewers were in agreement. Interpretations of what makes research innovative vary, with some believing that disagreement about a proposal shows that it is innovative.[77] Nonetheless, applications were advanced primarily based on the average of their overall scores, and it is thus important to consider the extent to which reviewers agreed on applications.

7.5.1 Reviewers' Agreement by Award Stage

Calculations were performed to examine reviewer agreement when application score data are organized by award stage. Agreement among reviewers ranged from moderate to very good across the three years (Exhibit 58).

Exhibit 58. Reviewer Agreement on Applications by Award Stage, FY 2007–2009

Brennan-Prediger Coefficients by Award Stage	2007	2008	2009 X02	2009 DP2
Applicant	0.55	0.49	0.48	N/A
Finalist	0.84	0.62	0.56	0.53
Awardees	0.83	0.70	0.61	0.47

Source: Application scores by each reviewer were provided by NIA program staff.

Note: The scale for the Reviewer Agreement of the scores is: <0.2 = poor; 0.21–0.40 = fair; 0.41–0.60 = moderate; 0.61–0.80 = good; and 0.81–1.0 = very good. The scores from a total of 296 applications were not included in the calculation of reviewer agreement by award stage, and all subsequent B.P. Coefficients, because scores from one or more reviewers were missing.

It was expected and generally observed that reviewer agreement increased across each award stage.[78] Finalists and awardees likely advanced because their Average Overall Scores were higher, and an application's Average Overall Score would likely be higher when all of its reviewers agreed on the high score of the application. Despite the increase in agreement across award stages, inter-rater agreement in general decreased across the first three years (Exhibit 58).

The FY 2009 Phase II (DP2) inter-rater reliability diverged notably from the trend of increasing agreement across each award stage in that agreement between reviewers was shown to be lower for awardees than for finalists. The process of choosing finalists and awardees in FY 2009, however, differed greatly from that of previous years. The Phase II (DP2) reviewers, in collaboration with NIA leadership, participated in a conference call following the submission of their scores, where they were allowed to alter the final application rankings that had previously been based solely on the Phase II (DP2) Average Overall Scores. The Phase II (DP2) application scores did not change after reviewers reached a consensus on the final rankings, but recommendations to the Advisory Committee to the Director for award funding may have been less reliant on Average Overall Scores than in previous years based on the teleconference discussion. Additionally, Dr. Collins made selections of additional awardees due to the availability for ARRA funds, and these selections were based on strategic priority areas for NIH. All of

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[77] C. F. David Kaplan, "Statistical analysis in NIH peer review—identifying innovation," *The FASEB Journal*, 2007; **21**:305-308.

[78] In FY 2007 and in Phase II (DP2) in FY 2009, reviewer agreement was higher for finalist than for awardees (Exhibit 60).

these reasons may contribute to explaining why reviewer agreement on scores for FY 2009 Phase II (DP2) awardees was lower than that for the finalists.

7.5.2 Reviewer Agreement by Research Area

Reviewers' agreement on application scores by applicant research area is shown in Exhibit 59. Agreement among reviewers within research areas varied from fair to good, and no single research area had high agreement every year. This finding indicates that having all reviewers in the same area as the application does not necessarily produce high inter-rater reliability, as one might expect.

Exhibit 59. Reviewers' Agreement (Brennan-Prediger Coefficients) by Application Research Area

Research Area	2007	2008	2009 X02	2009 DP2
Behavioral and Social Science	0.52	0.46	0.36	0.65
Cellular Biology (FY 2007)	0.50	N/A	N/A	N/A
Chemical Biology	0.65	0.66	0.51	0.47
Clinical and Translational Research	0.53	0.56	0.59	0.50
Epidemiology	0.36	0.52	0.39	0.38
Immunology (FY 2008–2009)	N/A	0.63	0.42	0.36
Instrumentation and Engineering	0.63	0.39	0.47	0.61
Molecular Biology (FY 2007)	0.60	N/A	N/A	N/A
Molecular and Cell Biology (FY 2008–2009)	N/A	0.48	0.46	0.47
Neuroscience (FY 2008–2009)	N/A	0.49	0.52	0.64
Pathology (FY 2007)	0.58	N/A	N/A	N/A
Physiology and Integrative Systems	0.53	0.38	0.60	0.39
Quantitative and Computational Biology	0.53	0.33	0.60	0.39

Source: Application research areas and scores were provided by NIA program staff.

Notes: The scale for the Reviewer Agreement of the scores is: <0.2 = poor; 0.21–0.40 = fair; 0.41–0.60 = moderate; 0.61–0.80 = good; and 0.81–1.0 = very good. "N/A" indicates that the Research Area was not present in the year shown.

7.5.3 Reviewers' Agreement by Review Criterion

Reviewers' agreement across application scores for each of the three review criteria and the Overall Score is presented in Exhibit 60. Reviewer agreement was generally moderate for all three criteria but reviewers diverged with respect to the Innovativeness criterion in FY 2007–2008, and in Phase I (X02) in FY 2009. This finding supports what was heard in reviewer interviews that reviewers often considered the Innovativeness criterion most critically, and that there was no consensus on how innovation is defined or recognized.[79]

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[79] More details can be found in Section 6.2.2.

**Exhibit 60. Reviewer Agreement in Assigning Criterion and Overall Scores
(Brennan-Prediger Coefficients), FY 2007–2009**

Brennan-Prediger Coefficient	2007	2008	2009 X02	2009 DP2
Scientific Problem	0.50	0.47	0.52	0.55
Innovativeness	0.47	0.39	0.44	0.54
Investigator Qualifications	0.56	0.54	0.57	0.60
Overall Score	0.55	0.49	0.48	0.53

Source: Application scores by each reviewer were provided by NIA program staff.

Note: The scale for the Reviewer Agreement of the scores is: <0.2 = poor; 0.21–0.40 = fair; 0.41–0.60 = moderate; 0.61–0.80 = good; and 0.81–1.0 = very good.

7.6   Finalist Advancement

7.6.1   Relationship between Scores and Finalist Advancement

The results of the score distributions show that the selection of NIA finalists and awardees were not based entirely on the Average Overall Score alone. NIA Program leadership explained that the Average Overall Scores were used to rank the applications from highest to lowest-scored, and applications at the top of the ranking were selected to advance as finalists. The next highest scored-applications were further reviewed with regard to the number of Top 4 votes received, their existing and previous NIH research funding, their potential for other funding (e.g., applicants who received R01s while in consideration for NIA were deemed ineligible), and to whether the finalist list was properly balanced in terms of research areas represented, as well as gender and race/ethnicity.[80] However, a STPI analysis done on the applicants who were advanced to the finalist round versus those with similar scores who were not advanced did not reveal any statistically significant differences between the groups in terms of race, ethnicity, gender, or research area. Thus, the advancement of an applicant to a finalist cannot be predicted solely from the average Overall Scores and the Top 4 designation (Exhibit 61), or from other demographic characteristics.

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[80]   Interview with NIA Program Leadership, January 4, 2010.

Exhibit 61. Likelihood of Finalist Advancement Based on Scores, FY 2007–2009 (Percentage of Applications that Advance to Final Review)
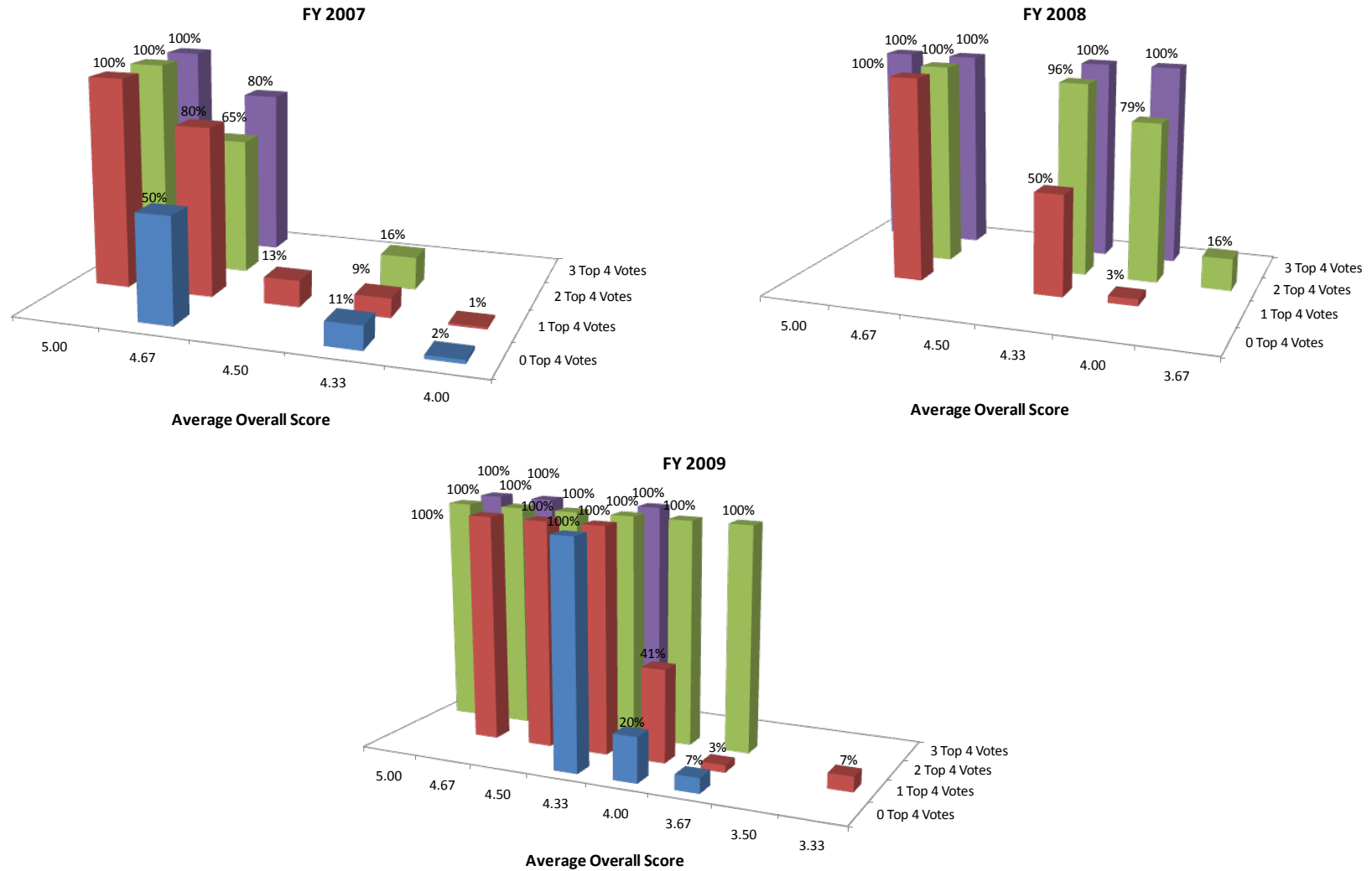
Source: Application scores the number of Top 4 votes given by each reviewer were provided by NIA program staff.

Note: The chart shows the percentage of applicants who advanced as finalists, based on Average Overall Scores and number of Top 4 votes. Applicants with higher scores and more Top 4 votes most frequently advanced.

7.6.2 Final Selection of Awardees

In the first two years of the program (FY 2007 and FY 2008), along with a set of IC directors, NIA program leadership reviewed the applications' scores and comments provided by the external reviewers, before ranking them into three tiered categories: fund, fund if additional funds are available, and do not fund. Consideration was made as to whether an IC would be interested in co-funding a finalist.[81] The final recommendations were then sent to the Advisory Committee to the Director and the Director himself, who followed the recommendations for selecting awardees.

As described Chapter 3, the selection process was changed in FY 2009, and in that year, the Phase I (X02) process was exactly as it had been in previous years. However, when determining finalist advancement, NIA program leadership relied only on the Average Overall Scores and Top 4 votes to determine which applicants advanced as finalists. These finalists were then invited to submit a Phase II (DP2) application (which was the same as the X02 application, except applicants could make changes to their biosketch), and these applications were set to a second round of external reviewers. Following Phase II (DP2), program leadership ranked the finalist applications based on their DP2 Average Overall Scores, and the tiered ranking was then discussed with the external reviewers via a teleconference, in which finalists could be moved from one tier to another based on the consensus of the group. The final tiered ranking, with the same three recommendations (fund, fund if additional funds are available, or do not fund), was sent to the Advisory Committee to the Director and the Director himself. In FY 2009, additional funds were available because of ARRA, and the new NIH Director also selected certain finalists for funding based on their alignment with strategic NIH priorities. In FY 2009, all eligible finalists in the top tier were funded,[82] and more awards were granted as additional funds became available.

Thus, the final selection of the awardees was not based entirely on the scores provided by external reviewers. Discretion was used by NIA program leadership and by the NIH Director to select awardees based on internal NIH-wide and IC-specific priorities.

7.7   Summary of Scoring Analyses

Analyses in this chapter examine the advancement of finalists and the selection of awardees, and investigate how trends in application scores affected the selection process over the first three years of the NIA.

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[81] In FY 2008, Dr. Zerhouni encouraged ICs, by stating that if an IC funded 1/3 of an award, the Office of the Director would fund the other 2/3. This resulted in more co-funding that year, with 14 awardees co-funded compared to 1 in FY 2007 and 3 in FY 2009. A list of awardees that were co-funded by ICs is included as Appendix XX.

[82] Two finalists in the top tier became ineligible.

Regarding the Overall Scores and the criterion scores:

- The three criterion scores are aligned (positively correlated) with the Overall Scores, and the score for "Innovativeness," had the strongest correlation, which was expected as interviewed reviewers reported evaluating the Innovativeness criterion most critically when assigning the Overall Score.
- The Overall Scores and Average Overall Scores for all applicants, appear unimodal and symmetric for FY 2007, FY 2008, and FY 2009 Phase I (X02). In FY 2009, although applicants who advanced as finalists predominately earned high Overall Scores in Phase I (X02), scores in Phase II (DP2) were redistributed to a unimodal and symmetric distribution. This finding supports feedback received during reviewer interviews that reviewers first read all of their applications before assigning scores, in order to calibrate the application pool.

Scores by demographic characteristics:

- Men received significantly higher scores and more Top 4 votes per applicant than women in FY 2007.
- Applications in Behavioral and Social Sciences received significantly lower scores in FY 2007, but there were no significant differences in scores across research areas in other years.

Regarding inter-rater reliability:

- Agreement among reviewers increased for each stage of the award (applicant, finalist, and awardee), but overall agreement decreased over time from FY 2007–2009.
- Agreement among reviewers within research areas varied from fair to good.
- Reviewer agreement also ranged from fair to moderate when assigning each of the criterion scores and the Overall Score.

Regarding the final selection process:

- In all three years, applicants with the highest Average Overall Scores and the most Top 4 votes had the highest likelihood of advancing as finalists.
- Although the tiered ranking was primarily based on the Average Overall Scores and Top 4 votes, the final selection of awardees was not solely based on scores, as discretion was used by NIA program leadership and by the NIH Director to select awardees based on internal NIH-wide and IC-specific priorities.

8. Findings and Recommendations

Our findings and recommendations, drawn from the analyses documented in the preceding chapters, are based on a careful examination of the data collected as part of the process evaluation. The findings center around the three areas of study questions: Program Design and Implementation (Findings 1–6), Program Participation (Findings 7–9), and Program Evolution (Finding 10). Findings are presented only when changes to the program may be worthy of consideration (i.e., where aspects of the program processes seem to be working, no findings are presented). Recommendations are provided only when the finding is actionable.

8.1 Program Design and Implementation

Finding 1: The NIA program was loosely based on the NDPA program. The NIA program is largely modeled on the flagship program of the Roadmap for Medical Research, the NIH Director's Pioneer Award (NDPA), yet there are key differences in the program design. Some of these differences were a result of the short time available to put the program in place during the first year of the program, but it is unclear as to why other differences, such as letters of reference, were not incorporated in future years of the program. In general, there may be issues inherent in general application of the NDPA design for a program intended for new investigators.

Finding 2: The goals for the NIA program are broad, and could include a range of specific objectives. The NIA program defines its goals in the program RFA: the program aims to stimulate highly innovative research and support promising new investigators. While they are clear, these goals can be realized in many different ways: providing additional funding for innovative work by early-stage NIH investigators; bringing in creative investigators who would not normally turn to the NIH for support; providing funding to test the feasibility of a new line of research that is a larger amount than an R21; encouraging creative investigators without R01-type funds to pursue their ideas; and recognizing early-stage talent. Because the goals of the program are broad, all these pathways are open to potential applicants of NIA.

Finding 3: Program participants found the goals of the program to be clear, but had additional expectations. On the whole, NIA applicants and reviewers stated that the program goals were clear. Upon further inspection, we found that they had additional expectations of what the program should provide. The program is not structured to specifically support the career advancement of new investigators—it is assumed to happen through the advancement of the research agenda of the new innovator. However, applicants and awardees had expectations for more direct support of career advancement, with some applicants requesting feedback on their application when they were unsuccessful, and some awardees wishing for more mentoring from the program. The program is not set up to meet this objective, and there are no program activities that are specific to supporting career advancement.

Recommendation: Three years into its implementation, with the benefit of data and hindsight, NIA program leadership should more thoroughly consider the program's logic, and decide whether the current program design suffices. This consideration could be done informally, in a discussion amongst

program leadership, or more formally through a working group as was done for the NDPA program. As part of the exercise, NIA program staff may also wish to review program announcement language, and add clarity around what the NIA program provides and does not provide. This should help to manage applicant and awardee expectations. With respect to career advancement, as part of its review of the program design logic, NIA should consider whether there should be any activities to support career advancement.

Finding 4: NIA's approach of using average overall score as a selection tool precludes applications that reviewers disagreed on, which may include some innovative applications. To select finalists and awardees, the overall scores of an application are averaged across the three reviews, and program staff select proposals with the highest total scores as finalists. This implies that applications with the least amount of disagreement are considered by the program to be the most innovative. Without explicitly saying so, the NIA program is assuming that reviewers would agree on qualities such as "innovativeness" of the proposed project.

Recommendation: NIA may consider taking a second look at applications that have the broadest range of scores. To test the hypothesis that risky research is likely to have greater disagreement, an additional recommendation is to run a pilot in future years with a larger number of reviewers reviewing an application.

Finding 5: Although some reviewers stated that preliminary data in an application affected their review and most applicants submitted preliminary data, there is no evidence that collecting preliminary data increased the odds of applicants advancing in the selection process. The NIA program stated that preliminary data could be included as part of an application, but that it was not required. The majority (~80%) of NIA applicant survey respondents stated that they collected preliminary data prior to submitting their applications, and many reviewers considered it in their review of the applications. Our analysis showed that collecting preliminary data did not improve the odds of being awarded the NIA.[83] Collecting preliminary data may in fact do more harm than good by, for example, discouraging researchers from submitting applications if they do not have preliminary data. The ten-page requirement for the application may also encourage applicants to submit preliminary data, as opposed to the five-page requirement in the NDPA program.

Recommendation: The NIA program should consider the purpose of preliminary data. If the program is looking for wholly new ideas, the NIA program should consider not allowing the submission of preliminary data as part of the application. This would also further differentiate the NIA program from the traditional R01 program. If the program would like to allow both new ideas and new investigators with preliminary data who wouldn't normally be funded by an R01, the program could consider reviewing those applications that do not contain preliminary data in a separate pool from those that do, so that reviewers are not biased by the presence or absence of preliminary data.

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[83] This finding must be viewed with caution, as it relies on self-reported measures of whether preliminary data were collected prior to applying, and not on an objective measure of which applications did in fact contain preliminary data.

Finding 6: The majority of proposals, especially those funded, were viewed as being as being innovative and outside the realm of convention. Reviewers characterized only about 10% of the proposals as neither innovative nor outside the realm of convention. Reviewers thought that the combination of review criteria (PI qualifications, innovation, and scientific problem) to be important in their assessment of proposals, but among the three criteria, ranked innovation as the most important.

Finding 7: Certain aspects of the program's activities, including the flexibility of the funds and the allocation of all funds up front, are viewed by awardees as being very useful for new investigators. Although NIA funds were originally disbursed at the start of the award due only to budgetary reasons, and this feature was not considered to be a factor to support new investigators, NIA awardees applaud this aspect of the program. Awardees indicated that the flexibility in how and when the funds can be used greatly aids their ability to build a research group and undertake other activities important to accomplishing their research and advancing as independent scientists.

Recommendation: The up-front disbursal of award funds should be continued as part of program administration. In addition, the outcome evaluation of the NIA program should test the role of the flexibility of funds in achieving innovative research results. The ongoing feasibility study of an outcome evaluation should explore how such a test could be performed, with possible comparison groups.

8.2   Program Participation

Finding 8: Most NIA applicants and awardees did not have previous NIH funding. Data show that approximately three-quarters of NIA applicants and awardees did not have previous NIH funding. Whether these applicants are scientists who would traditionally turn to the NIH for funding yet are just early in their careers, or whether they are scientists who would not have considered the NIH for funding (either because they would seek more "innovation-enabling" sources such as private foundations, or because they are in research areas typically not supported by the NIH) is unknown. The NIH outreach for the NIA and NDPA attempts to reach out to research groups who may not usually apply for NIH funding. NIA has reached a community that is predominantly new to the NIH.

Finding 9: Over the three-year period, the demographic distribution of NIA awardees reflected that of the applicant pool with respect to gender, seniority, race/ethnicity, and subject area distribution. The NIA program sought to have a diverse pool of applicants by encouraging women and underrepresented minorities to apply and by accepting applications from a diverse set of research areas. Applicants and awardees alike were about seven years out of their doctoral programs. The awardee pool was similar to the applicant pool in all respects.

Finding 10: Many reviewers stated they would have liked to have more engagement from the NIA program, including feedback on whether their scores were useful and more information on who was awarded the NIA. Reviewers for the NIA are eager to know how their reviews compare to those of other reviewers, and to how their applications fared overall. Many reviewers were unaware as to who was awarded, but stated they would be interested in being provided this information by the NIA program.

Recommendation: NIH may wish to more clearly communicate to reviewers what they should expect regarding feedback and interaction. NIH may consider low-burden ways to engage the reviewers, such as inviting them to the annual NDPA symposium.

8.3   Program Evolution

Finding 11: The two-phase review process instituted in FY 2009 caused some confusion to reviewers, who were unclear as to the purpose of each phase. In FY 2009, a two-phase system was put in place. Interviews with reviewers revealed that there were differing interpretations as to the purpose of the two phases. Despite the fact that interviewers were instructed to use the same review criteria in both phases, some reviewers stated that the first phase was to filter out those applications that did not have scientific merit, with the second phase focusing on the innovativeness of the applications. Other reviewers stated that the opposite was true—the first phase focused on innovation, with reviewers in the second phase taking a closer look at scientific merit.

Recommendation: The NIH should provide better guidance to reviewers on the purpose of each phase.

8.4   Conclusions

In this study, we evaluate the implementation of the New Innovator Award with regards to program goals. To do this, we reviewed the origins of the program and changes over the first three years, examined the characteristics and perceptions of applicants and external reviewers, and analyzed the scoring of the applications. We find that the first three years of the NIA program have been implemented without significant challenges. While applicants and reviewers were generally pleased with their participation in the program, there was some minor dissatisfaction expressed about feedback and follow-on funding; this can most likely be addressed by implementing the recommendations presented above. Importantly, reviewers felt that the proposals were innovative with only 10% saying that they were not innovative nor outside the realm of convention. Finally, our analysis shows that applicants and reviewers believe overall that the NIA program is adding value to the NIH portfolio.

Appendix A. Research Projects of Awardees

Exhibit A-1. FY 2007 NIA Awardees and Project Titles

2007 Awardees	Institution Name	Project Title
Kjersti Aagaard-Tillery	Baylor College of Medicine	Characterization of the Fetal Primate Epigenome and Metabolome Under In Utero Conditions of Maternal Obesity
Ryan Bailey	University of Illinois Urbana-Champaign	Personalized Clinical Diagnostics and Beyond: Integrated Ring Resonator Arrays
Edward Boyden	Massachusetts Institute of Technology	Novel Tools and Principles for Precisely Controlling Brain Activity
Frances Champagne	Columbia University New York Morningside	Epigenetic Mechanisms Mediating the Inheritance of Reproductive Behavior
Sean Davies	Vanderbilt University	Transformed Probiotic Bacteria for Treatment of Chronic Diseases
Pedro Fernandez-Funez	University of Texas Medical Branch Galveston	Mechanisms of Prion Misfolding
Sarah Fortune	Harvard University	Variation in M. tuberculosis in response to host selection
Levi Garraway	Dana-Farber Cancer Institute	Defining Melanoma Therapeutic Avenues by Integrative Functional Genomics
Tawanda Gumbo	University of Texas Southwest Medical Center Dallas	Efflux Pump Inhibitors to Reduce Duration of Antituberculosis Therapy
Nir Hacohen	Massachusetts General Hospital	Revealing Pathogen-Sensing Pathways Using RNAi Libraries
Ekaterina Heldwein	Tufts University	Structural and Mechanistic Studies of Herpesvirus Entry into Host Cells
Konrad Hochedlinger	Massachusetts General Hospital	Reprogramming of Somatic Cells by Defined Factors
Kristen Jacobson	University of Chicago	From Neighborhoods to Neurons and Beyond
Joanna Jankowsky	California Institute of Technology	Selective Neuronal Silencing to Study Cognitive Decline in Alzheimer's Disease
Alan Jasanoff	Massachusetts Institute of Technology	Genetically-Controlled MRI Contrast Agents for Functional Brain Imaging
Mark Johnson	Brigham and Women's Hospital	MicroRNA Biogenesis and the Cancer Proteome
Manuel Llinas	Princeton University	Novel Antimalarial Strategies using Metabolomic Network Discovery
Feroz Papa	University of California San Francisco	New Tools to Measure and Correct Endoplasmic Reticulum Stress in Single Living Cells
Dana Pe'Er	Columbia University	Genetic Variation and Regulatory Networks: Mechanisms and Complexity
Kathrin Plath	University of California Los Angeles	Chromatin and Epigenetic Inheritance

2007 Awardees	Institution Name	Project Title
Michael Rape	University of California Berkeley	Ubiquitin-Dependent Mechanisms of Tissue-Specific Cell Cycle Control
Jody Rosenblatt	University of Utah	Identification of Signals that Extrude an Apoptotic Cell from an Epithelium
Alan Saghatelian	Harvard University	Discovery Metabolite Profiling of the Prolyl Peptidases
James Shorter	University of Pennsylvania	Amyloid Elimination by Hsp104 and Substrate-Optimized Variants
Dorothy Sipkins	University of Chicago	Stem Cell, Tumor and Bone Marrow Microenvironment Cross-Talk in vivo
David Spiegel	Yale University	Small-Molecule Antibody Recruiting Therapeutics for Treating Human Disease
Eva Szigethy	University of Pittsburgh at Pittsburgh	Understanding and Treating Neuropsychiatric Symptoms of Pediatric Physical Illness
Derek Toomre	Yale University	Novel TIRF Microscopy for Analyzing Trafficking and Signaling at the Cell Cortex
Jing Yang	University of California San Diego	Epithelial-Mesenchymal Transition in Tumor Metastasis
Mehmet Yanik	Massachusetts Institute of Technology	Development of On-Chip Ultra High-Throughput Whole-Animal Assay Technologies

Source: NIA Website: 2007 New Innovator Award Recipients, http://nihroadmap.nih.gov/newinnovator/Recipients07.asp.

Exhibit A-2. FY 2008 NIA Awardees and Project Titles

2008 Awardees	Institution Name	Project Title
Zev Bryant	Stanford University	Engineering Molecular Motors
Ronald J. Buckanovich	The Regents of The University of Michigan	Using Embryonic Stem Cells to Re-create a Human Tumor Microenvironment to Develop Ovarian Cancer Therapeutic and Diagnostic Tools
Timothy J. Cardozo	New York University School of Medicine	Chemical Biology Design For Malaria
Karen L. Christman	University of California San Diego	Engineering a Dynamic Extracellular Matrix Microenvironment
Brian A. Cobb	Case Western Reserve University	T cell Dependent Immune Responses to Carbohydrate Antigens
Ronald D. Cohn	Johns Hopkins University	Maintenance of Skeletal Muscle Mass: Lessons Learned from Hibernation
Xiangfeng Duan	University of California Los Angeles	Integrated Free-Standing Nanoprobes for Neuroscience and Beyond
Seth J. Field	University of California San Diego	Phosphoinositides Provide Unique Insights into Cell Biology and Pathophysiology
Zemer Gitai	Princeton University	Discovering Antibiotic Drugs & Targets via High-Throughput Bacterial Cell Biology
Aaron D. Gitler	University of Pennsylvania School of Medicine	Using Yeast Cells to Define Mechanisms of Human Neurodegenerative Diseases
David H. Gracias	Johns Hopkins University	Minimally Invasive Micro-Nanoscale Tools and Devices for Medicine
Christy L. Hanes	University of Minnesota	Immune System-on-a-Chip for Quantitative Analysis of Cell Interactions During Allergy Response
Shelli R. Kesler	Stanford University School of Medicine	Assessment and Treatment of Cognitive Deficits in Breast Cancer
Yuriy Kirichok	University of California San Francisco	Molecular Biophysics of Mitochondrial Membranes: Defining Future Therapeutic Targets
Sanjay Kumar	University of California Berkeley	Cellular Mechanobiology: Biophysics and Therapeutics
Chay T. Kuo	Duke University Medical Center	Discovering Pathways Regulating Neurogenesis and Brain Remodeling After Injury
Lara K. Mahal	University of Texas at Austin	An Integrated Systems Approach to Deconstructing Glycosylation
Coleen T. Murphy	Princeton University	Slowing the Ticking Clock: C. elegans Screens for Reproductive Aging Regulators

2008 Awardees	Institution Name	Project Title
Ken-Ichi Noma	Wistar Institute	A New Methodology to Decipher Three-Dimensional Genome Structure
Melanie Ohi	Vanderbilt University Medical Center	Multifaceted Approaches for Studying the Structure and Function of Spliceosomes
Karin S. Pfennig	University of North Carolina Chapel Hill	The Origins and Maintenance of Context-Dependent Behavior
Miguel Ramalho-Santos	University of California San Francisco	Role of pluripotency in Development of the Germline
Samara L. Reck-Peterson	Harvard Medical School	Cellular Control of Microtubule-Based Transport: Unraveling its Molecular Mechanism
Erik Shapiro	Yale University School of Medicine	Single Cell MRI of Directed Cell Migration to Stroke
William M. Shih	Dana-Farber Cancer Institute	NMR Structure Determination of Membrane Proteins Enabled by DNA Nanotubes
Amy Jo Wagers	Joslin Diabetes Center	Aging and Rejuvenation of the Hematopoietic Stem Cell Niche
Jue D. Wang	Baylor College of Medicine	The Molecular Interface of Replication Elongation and the Cellular Environment
Lei Wang	Salk Institute of Biological Studies	Genetically Encoding Novel Amino Acids to Investigate Wnt Signaling in C. elegans
Joseph C. Wu	Stanford University School of Medicine	Inducing Pluripotency with MiRNAs: New Paradigm Shift in Cell Reprogramming
Sean M. Wu	Massachusetts General Hospital	Generation of Functional Organs Via Developmental Chimerism
Julia Zeitlinger	Stowers Institute for Medical Research	Investigating Developmental Potential Based on Genome-Wide Chromatin Status

Exhibit A-3. FY 2009 NIA Awardees and Project Titles

2009 Awardees	Institution Name	Project Title
Mark W. Albers	Massachusetts General Hospital	The Olfactory Neural Circuit as a Systems Level Model of Neurodegenerative Disease
Adah Almutairi	University of California San Diego	Chemically Amplified Response Strategies for Medical Sciences
Euan A. Ashley	Stanford University	Nanoscale Approaches to Allelic Silencing In Myocardial Disease States
Michel Bagnat	Duke University	Discovering New Regulators of CFTR and Fluid Secretion in Zebrafish
Gabor Balazsi	University of Texas MD Anderson Cancer Center	Connecting The Selection of Noisy Gene Expression Deviants to Genetic Evolution
Ipsita Banerjee	University of Pittsburgh at Pittsburgh	Defining Mechanisms Controlling Stem Cell Fate During Differentiation
Edward B. Brown, III	University of Rochester	Exploiting Collagen Organization to Predict and Prevent Tumor Metastasis
Fernando Camargo	Children's Hospital Boston	Analysis of Stem Cell Dynamics and Differentiation by Cellular Barcoding
Nikolaos Chronis	University of Michigan at Ann Arbor	A Biochip for Point-of-Care HIV/AIDS Diagnosis In the Developing World
Theodore H. Cohen	Brigham and Women's Hospital	Prevalence, Risk Factors and Consequences of Complex M. Tuberculosis Infections
Kathryn DeRiemer	University of California Davis	Transmission and Virulence ff Mycobacterium Tuberculosis
Elva D. Diaz	University of California Davis	Generation of Tumor Stem Cell Lines for Directed Therapeutics of Brain Cancer
Adam J. Engler	University of California San Diego	"Smart" Materials to Engineer a More Complete Stem Cell Niche
Alla Grishok	Columbia University	Investigating the Potential of Endogenous RNAi In Mediating Adaptation to Environment
Ira M. Hall	University of Virginia Charlottesville	Extent, Origin, and Control of Structural Variation in Mammalian Genomes
Sarah Heilshorn	Stanford University	Engineering 3D In Vitro Niches to Reveal Fundamentals of Cellular Biomechanics
Kerwyn Casey Huang	Stanford University	Engineering of Cell Shape and Intracellular Organization

2009 Awardees	Institution Name	Project Title
Sanjay Jain	Johns Hopkins University	Novel Imaging Biomarkers to Address Fundamental Controversies In TB Pathogenesis
Kevin A. Janes	University of Virginia Charlottesville	Stochastic Control of Abnormal Morphogenesis Induced by the ErbB2 Oncoprotein
Melissa Lambeth Kemp	Georgia Institute of Technology	Redox Regulation of Cellular Information Processing
Gabriel Kreiman	Children's Hospital Boston	Towards the Neuronal Correlates of Visual Awareness
Christopher Kristich	Medical College of Wisconsin	Genetic Approaches to Protein-Protein Interactions Mediating Antibiotic Resistance
Siavash K. Kurdistani	University of California Los Angeles	A Blueprint for Oncogenic Epigenetic Reprogramming
Naa Oyo A. Kwate	Columbia University	Immunologic Effects and a Structural "Countermarketing" Intervention: Racism, the HPA Axis, and African American Health
Kibum Lee	Rutgers University	Combinatorial Approaches for Studying Multiple Cues Regulating Human Pluripotent Stem Cell (hPSC) Fate
Daniel A. Lim	University of California San Francisco	Chromatin-Based Cellular Memory In Neural Stem Cells
Stavros Lomvardas	University of California San Francisco	Characterization of the Role of CpA Methylation In Neuronal Plasticity
Andre Guelman Machado	Cleveland Clinic Lerner College of Medicine of Case Western Reserve University	Deep Brain Stimulation of the Ventral Anterior Limb of the Internal Capsule for Modulation of the Affective Sphere of Chronic Neuropathic Pain
David Masopust	University of Minnesota Twin Cities	Maximizing CD8 T Cells for Protection
Jorge Rodrigo Mora	Massachusetts General Hospital	Reassessing the Physiological Role of Gut-Specific Lymphocyte Homing: Implication for Autoimmunity and Tolerance
Alysson R. Muotri	University of California San Diego	Modeling Autism with Human Pluripotent Cells Endothelial Progenitor and Tumor Cells to Study Angiogenesis and Metastasis in Cancer Development and Progression

2009 Awardees	Institution Name	Project Title
Sunitha Nagrath	Massachusetts General Hospital	Engineering Sensitive Microfluidic Multiplex Technology for Isolating Circulating
Vikas Nanda	Robert Wood Johnson Medical School	Computational Design of a Synthetic Extracellular Matrix
Diane Joyce Ordway	Colorado State University – Fort Collins	Immune Modulation by Highly Virulent Clinical Isolates of M. Tuberculosis
Aydogan Ozcan	University of California Los Angeles	Towards Mega-Throughput, Label-Free Genomics and Proteomics: Revolutionizing Microarray Technologies Using Lensless On-Chip Holographic Imaging and Nano-Plasmonics
Christine K. Payne	Georgia Institute of Technology	Intracellular Delivery and Targeting of Nanoparticles
Anna A. Penn	Stanford University	Fetal Brain Damage: a Placental Disorder
Patrick L. Purdon	Massachusetts General Hospital	A Neural Systems Approach to Monitoring and Drug-Delivery for General Anesthesia
Shu-Bing Qian	Cornell University	Engineering Ubiquitin Ligases to Investigate Protein Aggregation and Neurodegeneration
Wi-Jun Qian	Battelle Pacific Northwest Laboratories	A Universal Multiplex Assay System for High-Throughput Clinical Applications
Leon Reijmers	Tufts University	Molecular Analysis of Functional Neural Circuits
Theresa M Reineke	Virginia Polytechnic Institute and State University	Illuminating the Mechanistic Pathways of Polymer-Mediated Nucleic Acid Delivery
John Louis Rinn	Beth Israel Deaconess Medical Center	RNA and Chromatin Formation: from Discovery to Mechanism
Pardis Christine Sabeti	Harvard University	Host and Pathogen Evolution in Lassa Fever
Magali Saint-Geniez	Schepens Eye Research Institute	Bioengineering of Bruch's Membrane for the Treatment of Age-Related Macular Degeneration
Wenying Shou	Fred Hutchinson Cancer Research Center	Cellular Cooperation and Cheating: an Experimental and Mathematical Analysis
Justin L. Sonnenburg	Stanford University	Discovery of Gut Microbiota-Targeted Small Molecules: New Tools and Therapeutics

2009 Awardees	Institution Name	Project Title
Sohail F. Tavazoie	Rockefeller University	The Discovery of MicroRNAs that Predict Chemotherapeutic Responsiveness of Cancer
Jerilyn A. Timlin	Sandia National Laboratories	Multiplexed Measurements of Protein Dynamics and Interactions at Extreme Resoluti
Cho-Lea Tso	University of California Los Angeles	Cellular Quiescence and Brain Tumor Stem Cells
Erik M. Ullian	University of California San Francisco	The Role of Astrocytes In Plasticity and Disease
Vaiva Vezys	University of Minnesota Twin Cities	Understanding the Persistence of Immune-Mediated Chronic Diseases
Leor S. Weinberger	University of California San Diego	Developing Transmissible Antivirals by Exploiting Gene-Expression Circuitry
Chun-Li Zhang	University of Texas Southwest Medical Center Dallas	Neurogenesis de Novo in the Adult Central Nervous System

Source: NIA website: 2009 New Innovator Award Recipients,
http://nihroadmap.nih.gov/newinnovator/Recipients09.asp.

Appendix B. Study Questions and Sources of Data

Exhibit B-1. New Innovator Award Process Evaluation Study Questions

High Level Study Questions by Domain/Areas of Inquiry	Detailed Study Questions	RFAs & program documents	Applicant materials	Scores and Comments from evaluators	IMPAC II	NIA and other NIH staff	NIA Oversight Committee	External Evaluators	FY2008-2009 NIA Applicant Survey	Program documents of other programs (NDPA, HHMI, etc.)
Program Design *Program Structure* 1. What was the origin of the NIA program? What was the structure of the program and how did it differ from other programs at the NIH?	1.1 What was the origin of the program?	X				X	X			
	1.2 What was the design of the program? Why was the program designed the way it was?	X				X	X			
	1.3 How was the design intended to attract highly creative new investigators with innovative ideas?					X	X			
	1.4 How does the structure of the program compare to other programs (both inside and outside NIH) for new investigators?	X				X	X			X

High Level Study Questions by Domain/Areas of Inquiry	Detailed Study Questions	RFAs & program documents	Applicant materials	Scores and Comments from evaluators	IMPAC II	NIA and other NIH staff	NIA Oversight Committee	External Evaluators	FY2008-2009 NIA Applicant Survey	Program documents of other programs (NDPA, HHMI, etc.)
Program Design ***Selection Criteria Design*** 2. How was the selection process designed? How were the selection criteria chosen and implemented?	2.1 What was the overall selection process? How does this process compare to that of similar programs?	X		X		X	X	X		X
	2.2 How were the characteristics such as "exceptionally creative new investigators," "highly innovative projects," and "potential for unusually high impact" defined and operationalized in the program announcement, selection criteria, and instructions to evaluators?	X		X		X	X	X		
	2.3 What modifications, if any, should be made to the selection process design in future years?					X	X	X		

High Level Study Questions by Domain/Areas of Inquiry	Detailed Study Questions	RFAs & program documents	Applicant materials	Scores and Comments from evaluators	IMPAC II	NIA and other NIH staff	NIA Oversight Committee	External Evaluators	FY2008-2009 NIA Applicant Survey	Program documents of other programs (NDPA, HHMI, etc.)
Program Implementation Selection Criteria Implementation 3. What were the demographic and scientific characteristics of the applicants? What were the applicants' perceptions of the NIA program and processes?	3.1 Were directions, selection criteria, and application processes clear to the applicants and evaluators?			X		X		X	X	
	3.2 How were the characteristics of "exceptionally creative new investigators," "highly innovative projects," and "potential for unusually high impact" interpreted by applicants and evaluators?	X		X		X	X	X	X	
	3.3 Did the evaluators find the review process adequate to demonstrate and judge qualifications?			X				X		
	3.4 Did the applicants believe the selection criteria were adequate and appropriate to identify "exceptionally creative new investigators"? Did they believe the selection criteria were adequate to identify "highly innovative projects"?								X	
	3.5 How were the selection criteria interpreted by the NIH committee performing the second level of review? How were they applied?			X		X				

High Level Study Questions by Domain/Areas of Inquiry	Detailed Study Questions	RFAs & program documents	Applicant materials	Scores and Comments from evaluators	IMPAC II	NIA and other NIH staff	NIA Oversight Committee	External Evaluators	FY2008-2009 NIA Applicant Survey	Program documents of other programs (NDPA, HHMI, etc.)
	3.6 Were interpretations and applications of the selection criteria consistent across evaluators?	X		X		X	X	X		
	3.7 What modifications, if any, should be made to the selection process implementation in future years?					X	X	X	X	
Program Implementation Execution of Plans 4. How was the program designed and implemented to reach new investigators?	4.1 Is the program being implemented as planned? If not, how and why is it being implemented differently?	X				X	X			
	4.2 Were there concerns about transparency in the selection process - either by applicants or evaluators? Why?							X	X	
	4.3 How can program processes be improved?					X		X	X	
	4.4 Was the feedback provided to applicants in FY2007 helpful? Did those who received feedback use it in either (a) a reapplication to NIA or (b) an application to another program?								X	

High Level Study Questions by Domain/Areas of Inquiry	Detailed Study Questions	RFAs & program documents	Applicant materials	Scores and Comments from evaluators	IMPAC II	NIA and other NIH staff	NIA Oversight Committee	External Evaluators	FY2008-2009 NIA Applicant Survey	Program documents of other programs (NDPA, HHMI, etc.)
Program Participation Evaluators 5. What were the demographic and scientific characteristics of the reviewers? What were the reviewers' perceptions of the NIA program and processes?	5.1 What were the disciplinary foci and demographics of the evaluators? How did evaluators review applications outside of their disciplinary foci?					X		X		
	5.2 How were the evaluators selected? Did the evaluators have previous experience as evaluators of programs for new investigators or for highly innovative projects?					X	X	X		
	5.3 Were the evaluators and NIH satisfied that the selection criteria were applied fairly and consistently by the evaluators?					X	X	X		
	5.4 Did the evaluators evaluate NIA proposals differently than they would proposals for other NIH programs?							X		
	5.5 Were the evaluators and NIH satisfied that the ideas and approaches selected to advance would not have been funded by other NIH programs?					X	X	X		
	5.6 How can evaluator selection be improved in future years of the program?					X	X			

High Level Study Questions by Domain/Areas of Inquiry	Detailed Study Questions	RFAs & program documents	Applicant materials	Scores and Comments from evaluators	IMPAC II	NIA and other NIH staff	NIA Oversight Committee	External Evaluators	FY2008-2009 NIA Applicant Survey	Program documents of other programs (NDPA, HHMI, etc.)
Program Participation Applicants and Awardees 6 What were the characteristics of the applications? How were awards chosen?	6.1 Did the program attract highly creative young researchers?		X		X	X		X		
	6.2 What were the disciplinary foci and other characteristics of the applicants (and awardees)?		X		X				X	
	6.3 Were the proposals submitted in areas different than the applicant's previous disciplinary area?		X						X	
	6.4 Did unsuccessful applicants from previous years reapply? If so, how did their applications change? If not, why not?				X				X	
	6.5 Did the program attract any applicants who a) had never before worked on projects supported by NIH; and b) had never before applied for NIH funding?				X				X	
	6.6 Did the pool of applicants meet the expectations of NIH and the evaluators?			X		X	X	X		
	6.7 What factors differentiated awardees from applicants?		X			X		X	X	

High Level Study Questions by Domain/Areas of Inquiry	Detailed Study Questions	RFAs & program documents	Applicant materials	Scores and Comments from evaluators	IMPAC II	NIA and other NIH staff	NIA Oversight Committee	External Evaluators	FY2008-2009 NIA Applicant Survey	Program documents of other programs (NDPA, HHMI, etc.)
Program Participation ***Project Proposals*** 7. What about the submitted proposals (and especially those selected for awards) showed innovativeness?	7.1 Did the evaluators believe the submitted proposals were innovative? Did they believe they were different than proposals submitted to other NIH programs? Did the evaluators believe the awarded proposals were innovative?			X				X		
	7.2 Did the applicants believe the submitted proposals were for highly innovative projects? Did the applicants believe the awarded proposals were for highly innovative projects?		X						X	
	7.3 If applicants simultaneously submitted a proposal to other NIH programs, were the proposals to NIA for the same project? How did the proposals differ?				X				X	
	7.4 Did applicants simultaneously apply for other funding from NIH? Were these proposals for the same research?				X				X	
	7.5 Did the applicants propose ideas and approaches they believe would not have been funded elsewhere (at NIH and beyond)?								X	

High Level Study Questions by Domain/Areas of Inquiry	Detailed Study Questions	RFAs & program documents	Applicant materials	Scores and Comments from evaluators	IMPAC II	NIA and other NIH staff	NIA Oversight Committee	External Evaluators	FY2008-2009 NIA Applicant Survey	Program documents of other programs (NDPA, HHMI, etc.)
Program Evolution/Program Evolution 8. How did the program's design, implementation, and participation evolve over the first three years?	8.1 How and why did the program design evolve from the preceding year?	X				X	X			
	8.2 What was the rationale for program changes and what were their intended effects on the process and outcome?	X				X	X			
	8.3 Did the evaluators and NIA staff believe there was a difference in project proposals from the preceding year?					X	X	X		

Appendix C. Summary of Statistical Analyses

Exhibit C-1. Summary of Statistical Analyses

Statistical Test	Summary	Purpose	Key Variables	Results
Odds Ratios	Odds ratios are used to quantify the relationship between two binary variables. Specifically, odds ratios provide an estimate of the number of times an event of interest occurs relative to the number of times it does not occur. Source: Bland, JM and Altman, DG. "The Odds Ratio." *BMJ*. 2000 May 27; 320(7247): 1468.	Odds ratios were calculated to estimate the odds of advancing as a finalist or an awardee for individuals who reapplied to the NIA. Odds ratios were also used to estimate the odds of being awarded based on whether or not an applicant had previously received NIH funding, and whether an applicant reported collecting preliminary data before their application affected the applicant's chance of being awarded.	The award status (applicant, finalist or awardee) for individuals who reapplied to the program, and for first-time applicants. Also, we used the award status of individuals who previously received NIH funding, and applicants who reported collecting preliminary data through the applicant survey.	In FY 2008, being a re-applicant was associated with an increased chance of being awarded. Having previously received an R21 award slightly increased an applicant's chances of being awarded. There was no evidence that individuals who reported collecting preliminary data, in preparing their application, had higher odds of being awarded.
Fisher's Exact Test	A Fisher Test is a non-parametric test used for categorical data to determine whether two or more different samples all follow the same distribution. Fisher, R. A. (1922). "On the interpretation of χ^2 from contingency tables, and the calculation of P". *Journal of the Royal Statistical Society* **85** (1): 87–94	The Fisher's Exact Test was used to determine whether there were statistically significant differences between the distributions of various demographic characteristics for applicants, finalists, and awardees.	Gender, race, ethnicity, doctoral degree and research area distributions for all applicants, finalists and awardees by year.	There were no significant differences in the distributions of gender, race, ethnicity, and research area by application phase (e.g. applicant, awardee, or finalist). However, fewer MDs received NIA awards than expected based on the total applicant pool.

Statistical Test	Summary	Purpose	Key Variables	Results
Exact Binomial Test	A binomial exact test determines the probability that the proportion of a binomial sample is significantly different from the population of interest. It is also assumed that the population is binomial. Source: Clopper, C. J. & Pearson, E. S. (1934). The use of confidence or fiducial limits illustrated in the case of the binomial. *Biometrika*, **26**, 404–413	The binomial exact test was used to compare the gender ratio of NIA awardees to the ratio of male and female awardees of R01 equivalent grants in each year.	Gender of NIA awardees each year, and the ratio of male and female R01 recipients.	Evidence suggests that there was no difference between gender proportions of NIA awardees and recipients of R01 equivalent grants in FY 2007 – 2009.
Spearman's Rank Correlation Coefficient	Spearman's correlation is a number between -1 and 1 that describes the degree of association between two ordinal variables, or how the two variables behave together. Source: C. Spearman, "The proof and measurement of association between two things" Amer. J. Psychol., 15 (1904) pp. 72–101	A correlation was computed to determine the association between the Criterion Scores and the Overall Score for each application.	Each of the three criterion scores, and the Overall Scores for each application.	Across all three years, the Criterion Scores positively correlated with the Overall Score; namely, a positive relationship indicates that when criterion scores on an application were high, so was the Overall Score, and similarly, when the criterion scores were lower, so was the Overall Score.

Statistical Test	Summary	Purpose	Key Variables	Results
Permutation-based Difference in Means Test	The permutation-based difference in means test is a non-parametric test that determines whether or not there is a statistically significant difference in means between two samples. Although similar to a two-sample t-test, the main advantage of the permutation-based test is that it can be used for small sample sizes, and does not make any distributional assumptions. Source: Good, P.I. (2005). "Permutation, Parametric and Bootstrap Tests of Hypotheses." Springer-Verlag, New York.	The Permutation-based Difference in Means Test was used to test the difference between the number of Top 4 votes earned by women and the number earned by men. This test was also used to determine the differences between the average Overall scores on applications in each research area.	Top 4 votes for each applicant and their gender. Overall Scores and research area for each application.	Men earned more Top 4 votes per applicant than women, on average. In FY 2007, applications in Behavioral and Social Sciences had significantly lower average Overall Scores than applications in all other areas.
Mann-Whitney U Test	Mann Whitney U is a non-parametric test, generally used for ordinal data. The test is used to compare the means of two population group which come from the same population, to determine if the sample groups reflect the presence of a significant difference in the larger populations which they represent. Source: David F. Bauer (1972). Constructing confidence sets using rank statistics. *Journal of the American Statistical Association* **67**, 687–690	The Mann-Whitney U Test was used to determine the differences between the overall scores by the gender of the applicants.	Overall Scores for each applicant and their gender.	Men had significantly higher Overall scores than women.

Statistical Test	Summary	Purpose	Key Variables	Results
Brennan-Prediger Coefficients	The Brennan-Prediger (also known as the G-Index) is a measure of inter-rater agreement for a dataset with subjective judgments, with one indicating perfect agreement, and zero indicating no agreement. Source: Gwet, KL. "Computing inter-rater rater reliability and its variance in the presence of high agreement." *British Journal of Mathematical and Statistical Psychology* (2008), 61, 29–48.	BP Coefficients were calculated to measure agreement among reviewers' scores on applications, by each of the three criteria, the Overall Score, by research, and by award stage (applicant, finalist, and awardee).	Each of the three criterion scores, and the Overall Scores by each reviewer, as well as the research area, and award stage for each application.	Agreement among reviewers within research areas varied from fair to good, and no single research area had high agreement every year. Agreement when assigning scores by criterion was moderate, and agreement was higher for finalists and awardees than for applicants each year.

Appendix D. Survey of Applicants

National Institutes of Health
A Process Evaluation of the NIH Director's
New Innovator Award (NIA) Program

Survey Instrument—NIA

General Survey for Applicants (including Awardees)
Welcome to the NIA Candidate Survey. There are seven to nine sections in the survey. Please provide responses to the following questions to the best of your ability. You may choose not to answer specific questions and it will not affect your ability to submit the survey.

After completing a set of questions, please click "next" to view the next set of questions. If you would like to go back and change a response, you can use the "back" button on the survey or the pull-down menu at the bottom of the page. Please do not use your browser's navigation buttons.

If you would like to save and come back to the survey, click the "save" button at the bottom of any page. The survey should take approximately 15 minutes to complete.

Please consult the NIA website to review the Request for Applications (RFA), criteria, or processes: http://nihroadmap.nih.gov/newinnovator/

Please note that participation in this survey is entirely voluntary. Your decision to participate will have no effect on your current or future NIH funding status.

Your responses will be kept strictly confidential: If you choose to participate, respondent confidentiality will be protected to the extent provided by law, and STPI will report only aggregate information concerning overall impressions of the process to the NIH.

Additionally, you may click on underlined words in the survey, which are hyperlinked to the appropriate document. To begin the survey, scroll down and click "next."

1

New Innovator Award Applicant Survey [2007],[2008] and [2009]

|A| The Application Process – *Page 2*

What attracted you to the NIA program?
{Choose all that apply}
( ) The amount of the award
( ) The application was relatively short.
( ) The application allowed for more flexibility than more traditional grants.
( ) The NIA application did not require preliminary data.
( ) The program funds projects that might not be funded by more traditional grants.
( ) The program focuses on supporting creative new investigators
( ) The NIA is a prestigious award.
( ) Other [   ]

How did you hear about the NIA program?
{Choose all that apply}
( ) NIA/NIH website
( ) An announcement from NIH or an NIH component
( ) An announcement from my department
( ) An announcement from my institution's research office
( ) An announcement from a professional society
( ) Journal advertisement
( ) Flyer at a scientific meeting
( ) Federal Register
( ) Article in a scientific news outlet
( ) Word of mouth
( ) Other | |

Was the 200X NIA RFA ( ) clear in describing the kind of investigator (e.g. "exceptionally creative") or the kind of idea (e.g. "highly innovative") the program seeks to fund?
{Choose one}
( ) Completely clear
( ) Somewhat clear
( ) Somewhat unclear
( ) Completely unclear

(If somewhat clear, somewhat unclear, or completely clear) **What aspects were unclear?**
{Enter answer in paragraph form}
[

2

]

Do you believe the selection criteria in the 200X NIA RFA ( ) were appropriate for achieving the goals of the NIA program?
( ) Yes
( ) Somewhat
( ) No

(If somewhat or no) Please elaborate on how the selection criteria could be improved to better meet the goals of the NIA program.
[Enter answer in paragraph form]
[

]

As part of the application process, you were asked to classify your research into one of ten areas:

[2007]
1. behavioral and social sciences
2. clinical and translational research
3. instrumentation and engineering
4. molecular biology
5. cellular biology
6. chemical biology
7. pathogenesis
8. epidemiology
9. physiology and integrative systems
10. quantitative and computational biology

[2008] and [2009]
1. Behavioral and Social Sciences
2. Chemical Biology
3. Clinical and Translational Research
4. Epidemiology
5. Immunology
6. Instrumentation and Engineering
7. Molecular and Cellular Biology
8. Neuroscience
9. Physiology and Integrative Systems

3

10. Quantitative and Computational Biology

Were these ten areas adequate to choose from?
{Choose one}
( ) Yes
( ) No

Should other areas be offered? Which ones?
{Enter answer in paragraph form}
|

|

Although you were asked to classify your research into one of ten areas, which of the following research areas did your NIA-proposed research actually fall into?
{Choose all that apply}
[2007]
( ) Behavioral and social sciences
( ) Clinical and translational research
( ) Instrumentation and engineering
( ) Molecular biology
( ) Cellular biology
( ) Chemical biology
( ) Pathogenesis
( ) Epidemiology
( ) Physiology and integrative systems
( ) Quantitative and computational biology

[2008] and [2009]
( ) Behavioral and Social Sciences
( ) Chemical Biology
( ) Clinical and Translational Research
( ) Epidemiology
( ) Immunology
( ) Instrumentation and Engineering
( ) Molecular and Cellular Biology
( ) Neuroscience
( ) Physiology and Integrative Systems
( ) Quantitative and Computational Biology

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[A] The Application Process (continued) – *Page 3*

What preliminary work did you do prior to submitting your NIA application?
{Choose all that apply}
( ) I synthesized literature in the proposed research area
( ) I collected preliminary data for my research idea
( ) I collaborated with other researchers on collecting preliminary data
( ) I sought advice from colleagues
( ) I sought advice from an NIA or Pioneer Award winner.
( ) None of the above
( ) Other [   ]

(If they collected preliminary data) **Approximately how long did you spend on collecting preliminary data?**
{Enter answer in paragraph form}
[

]
{Choose one}
( ) Hours
( ) Weeks
( ) Months

Describe how your NIA-proposed idea came about and estimate for how long you have had it.
{Enter answer in paragraph form}
|

|

Do you believe that you were given an adequate opportunity to present your idea and display your qualifications in the application?
{Choose one}
( ) Yes
( ) Somewhat
( ) No

Please comment on what additional information you would have liked to provide, or if any information you provided seemed unnecessary.

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{Enter answer in paragraph form}

[

]

Did you have any difficulties with the electronic submission forms during the application phase?
{Choose one}

( ) Yes
( ) No
( ) I do not know, as I was not the one who submitted the electronic forms.

(If yes) **Please describe your difficulties:**
{Enter answer in paragraph form}

[

]

[B] 2009 DP2 Finalists - *Page 4 (To all 2009 applicants who were invited to submit a DP2 application)*

Our records indicate that you were selected as a DP2 finalist. Did you make any changes to your X02 pre-application before submitting it as a DP2 application?

( ) Yes
( ) No
( ) I do not recall

(If yes) **What changes did you make?**
{Enter answer in paragraph form}

[

]

[C] R01/R01-Equivalent Application in Same FY – *Page 5 (To all applicants and awardees that submitted a proposal for an R01 or R01-equivalent grant within the same fiscal year as the NIA proposal)*

Our records indicate that you submitted a proposal for an R01 (or R01-equivalent) grant within the same fiscal year as the NIA proposal. How similar was the idea you submitted for that grant to the idea submitted in your NIA application?
{Choose one}
    ( ) I submitted the same idea to both programs
    ( ) I made minor changes to my idea
    ( ) I made substantial changes to my idea
    ( ) I submitted a completely different idea

(If submitted the same or similar idea) **Please describe the differences between what you proposed to do for the NIA versus the R01.**

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[D] Proposed NIA Project - *Page 6*

(To all repeat applicants and awardees from FY07 to FY09) **Our records indicate that you have applied previously to NIA. How did the idea proposed in 2008 differ from your application in 2007?**
{Choose one}

( ) In 2008, I submitted a completely different idea than in 2007

( ) In 2008, I made substantial changes to the basic idea I proposed in 2007

( ) In 2008, I made minor changes to the basic idea I proposed in 2007

( ) In 2008, I submitted additional preliminary data to support the idea I proposed in 2007

( ) Other [   ]

Was the reviewer feedback on your 200X application appropriate?
{Choose one}

( ) Yes

( ) Somewhat

( ) No

*(if no or somewhat)***Please elaborate on how the reviewer feedback could be improved.**
{Enter answer in paragraph form}

[

]

(To all applicants and awardees that applied in FY08 and FY07, in FY09 and FY07, or in all three years) **For your most recent application, to what degree did you use the reviewer feedback provided on your 2007 application?**
{Choose one}

( ) Used extensively

( ) Used a little

( ) Took into consideration

( ) Did not use at all

Please share any other thoughts you have regarding the NIA review process.
{Enter answer in paragraph form}

|

|

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[D] Proposed NIA Project (continued) - *Page 6*

In your opinion, what is the likelihood that your NIA-proposed research would have been supported by any other funding sources (including NIH awards and others)?
{Choose one}
( ) Very likely
( ) Somewhat likely
( ) Somewhat unlikely
( ) Very unlikely

Why do you think your NIA-proposed research could or could not have been supported by other funding sources (NIH and beyond)?
{Enter answer in paragraph form}

Was the research in your proposed NIA project a significant departure from your previous research directions?
{Choose one}
( ) Yes
( ) No

In what way(s) did your proposed NIA project differ from your previous research directions?
{Enter answer in paragraph form}

Please indicate which of the following statements (if any) are true for the ideas you proposed to NIA in 200X:
{Choose all that apply}
( ) One or more of the fundamental ideas underlying my proposed research were at odds with prevailing wisdom
( ) My proposed research required use of equipment or techniques that have not been proven or are extraordinarily difficult
( ) My proposed research required knowledge of fields beyond my previously

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demonstrated area of expertise

( ) My research involved a novel combination of disciplines or an unprecedented scientific perspective

( ) None of these statements is true of my proposed research

Please indicate which of the following potential outcomes of scientific research apply to your proposed NIA idea in 200X:

{Choose all that apply}

( ) My proposed research could result in the formulation of new ideas or the advancement of theoretical concepts

( ) My proposed research could result in the discovery of new empirical phenomena

( ) My proposed research could result in the development of a new methodology, enabling empirical testing of theories

( ) My proposed research could result in the invention of novel instruments that would open up new research possibilities

( ) My proposed research could result in the new synthesis of existing ideas

( ) None of these statements is a potential result of my proposed research

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[E] Background/Funding Sources - *Page 7*

Please provide a rough estimate of the percentage of your total research funding (excluding in kind or indirect support) over the five years prior to your latest application submission for the NIA represented by each source below:
{Select the cell for the approximate percent of your total research funding.}

National Institutes of Health (NIH)
{Choose one}
- (x) 0
- ( ) 1-24%
- ( ) 25-49%
- ( ) 50-74%
- ( ) 75-100%

Other US Government Sources
{Choose one}
- (x) 0
- ( ) 1-24%
- ( ) 25-49%
- ( ) 50-74%
- ( ) 75-100%

Foundations (e.g. Howard Hughes Medical Institute, Ford Foundation, etc.)
{Choose one}
- (x) 0
- ( ) 1-24%
- ( ) 25-49%
- ( ) 50-74%
- ( ) 75-100%

Non-profit institutions (e.g. American Cancer Society, scientific societies such as Society for Developmental Biology)
{Choose one}
- (x) 0
- ( ) 1-24%
- ( ) 25-49%
- ( ) 50-74%
- ( ) 75-100%

Start-up funds from your own institution
{Choose one}
- (x) 0
- ( ) 1-24%
- ( ) 25-49%
- ( ) 50-74%

( ) 75-100%

For-profit companies
{Choose one}
   (x) 0
   ( ) 1-24%
   ( ) 25-49%
   ( ) 50-74%
   (x) 75-100%

Other (Please list sources below)
{Choose one}
   (x) 0
   ( ) 1-24%
   ( ) 25-49%
   ( ) 50-74%
   ( ) 75-100%

Please list OTHER sources:
{Enter answer in paragraph form}
[

|

Please list any significant IN KIND support/resources (i.e. non-monetary support) and its source:
{Enter answer in paragraph form}
|

|

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[F] Activities Since NIA Application Submission - *Page 8*

To what extent has applying to the NIA program significantly changed your future research direction(s)?
{Choose one}
( ) Completely
( ) To a large extent
( ) To some extent
( ) Not at all

***(If to some extent, to a large extent, or completely)* In what way(s) has your research direction changed?**
{Enter answer in paragraph form}
|

|

Which of the following have occurred since the time you applied to the NIA program?
{Choose all that apply}
( ) I received an award(s)
( ) I was promoted
( ) I have received tenure
( ) I am applying for tenure
( ) I published an original, peer-reviewed article
( ) I filed a patent application or have been granted a patent
( ) I received additional funding
( ) I expanded my research group
( ) I formed new partnerships/collaborations
( ) I changed my research focus
( ) I have expanded my research focus
( ) I changed institutions
( ) My work has been featured in the popular press and/or media
( ) Other [   ]

(For those who check 'I received an award') **What awards have you received since your NIA application?**
{Enter answer in paragraph form}
[

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]

(For those who check 'I changed my research focus' or 'I expanded my research focus)
In what way(s) has your research focus changed?
{Enter answer in paragraph form}
[

]
(For those who check 'I pushed an original, peer-reviewed article) **In which journal(s) did you publish your article?**

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[F] Activities Since NIA Application Submission (continued) - *Page 9 (Only to applicants)*

Despite not receiving the New Innovator Award, did you choose to pursue the research proposed in your NIA application?
{Choose one}
    ( ) Yes, in its entirety
    ( ) Yes, but only partially
    ( ) No

(If yes)
How were you able to work on the NDPA-proposed project?
{Choose all that apply}
    ( ) By using institutional funds
    ( ) By using other grants that I have
    ( ) I collaborated with a colleague who provides the funding
    ( ) I donated my time
( ) Other [   ]

Do you plan to reapply for an NIA in future years?
{Choose one}
    ( ) Yes
    ( ) No, I am no longer eligible
    ( ) No because [   ]

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[G] Your Impressions about the Success of the Program – *Page 10*

(For awardees only) **How many of the awarded projects**
(http://nihroadmap.nih.gov/newinnovator/Recipients08.asp,
http://nihroadmap.nih.gov/newinnovator/Recipients07.asp,
http://nihroadmap.nih.gov/newinnovator/Recipients09.asp) **do you believe are "highly innovative"?**
{Choose one}
    ( ) 0 to 25%
    ( ) 26% to 50%
    ( ) 51% to 75%
    ( ) 76% to 100%

(For awardees only) **Approximately how many of the awarded projects do you think could have been funded by more traditional funding sources such R01?**
{Choose one}
    ( ) 0 to 25%
    ( ) 26% to 50%
    ( ) 51% to 75%
    ( ) 76% to 100%

(For awardees only) **How familiar are you with the NIA awardees?**
{Choose all that apply}
    ( ) I have read the descriptions of their work on the NIA website.
    ( ) I have read their publications.
    ( ) I have met them at the annual Pioneer Award Symposium.
    ( ) I have attended their lectures/talks.
    ( ) Personal interactions/experience
    ( ) Other [   ]

(For awardees only) **Have you attended the annual Pioneer Award Symposium held at NIH?**

    ( ) Yes
    ( ) No
    ( ) No, but I plan to attend in the future.

(If yes or plan to attend in the future) **What benefits do you see in attending the Pioneer Award Symposium?**
{Choose all that apply}

    ( ) Opportunities to meet with NIH staff
    ( ) Opportunities to learn about other awardees' work
    ( ) Opportunities to form new collaborations
    ( ) Networking
    ( ) Other [   ]

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In your opinion, what are markers or characteristics of exceptionally creative investigators? Please give examples.
{Enter answer in paragraph form}

In your opinion, what are the characteristics of highly innovative research? Please give examples.
{Enter answer in paragraph form}

[H] Overall Assessment - *Page 11*

Overall, how satisfied were you with your experience with the NIA program?
{Choose one}
- ( ) Satisfied
- ( ) Somewhat satisfied
- ( ) Somewhat dissatisfied
- ( ) Dissatisfied

Please provide any additional comments or feedback related to the NIH Director's New Innovator Award.
{Enter answer in paragraph form}

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[I] Demographic Information - *Page 12*

Gender
{Choose one}
    ( ) Male
    ( ) Female

Ethnicity
{Choose one}
    ( ) Hispanic or Latino
    ( ) Not Hispanic or Latino

Race (Please mark all that apply)
{Choose all that apply}
    ( ) American Indian or Alaska Native
    ( ) Asian
    ( ) Black or African American
    ( ) Native Hawaiian or other Pacific Islander
    ( ) White

Age (Please select a range)
{Choose one}
    ( ) Under 20
    ( ) 20-24
    ( ) 25-29
    ( ) 30-34
    ( ) 35-39
    ( ) 40-44
    ( ) 45-49
    ( ) 50-54
    ( ) 55-59
    ( ) 60-64
    ( ) 65+

Completed tertiary degrees
{Choose all that apply}
    ( ) MD, Year [   ]
    ( ) PHD (or equivalent) , Year [   ]
    ( ) RN, Year [   ]
    ( ) VMD, Year [   ]
    ( ) VDOT, Year [   ]
    ( ) DVM, Year [   ]
    ( ) DOTH, Year [   ]
    ( ) DMD, Year [   ]
    ( ) DDS, Year [   ]
    ( ) Other, Year [   ]

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Did you complete a fellowship or residency?
{Choose one}
( ) Yes, in year | |
( ) No

As part of our study of highly creative researchers, we are requesting Curriculum Vitae (CVs) from survey participants. It would be invaluable to this evaluation if you would e-mail your CV to NIHsurvey@ida.org.

Thank you for completing the 2009 NIA Survey.

Please click "finish" below to submit your responses.

If you have any additional questions or comments, please feel free to email us at NIHsurvey@ida.org.

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Appendix E. Additional Applicant Survey Responses

Exhibit E-1. Applicant Survey Question: Please indicate which of the following statements (if any) are true for the ideas you proposed to NIA in 200X.
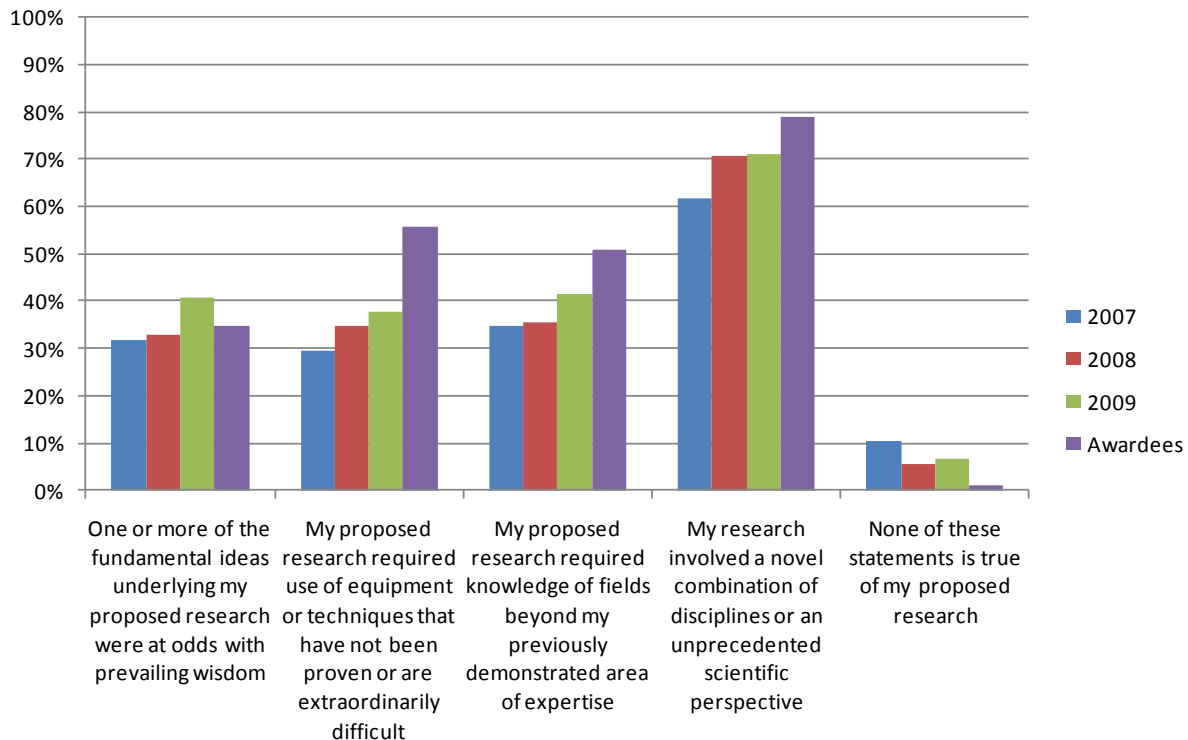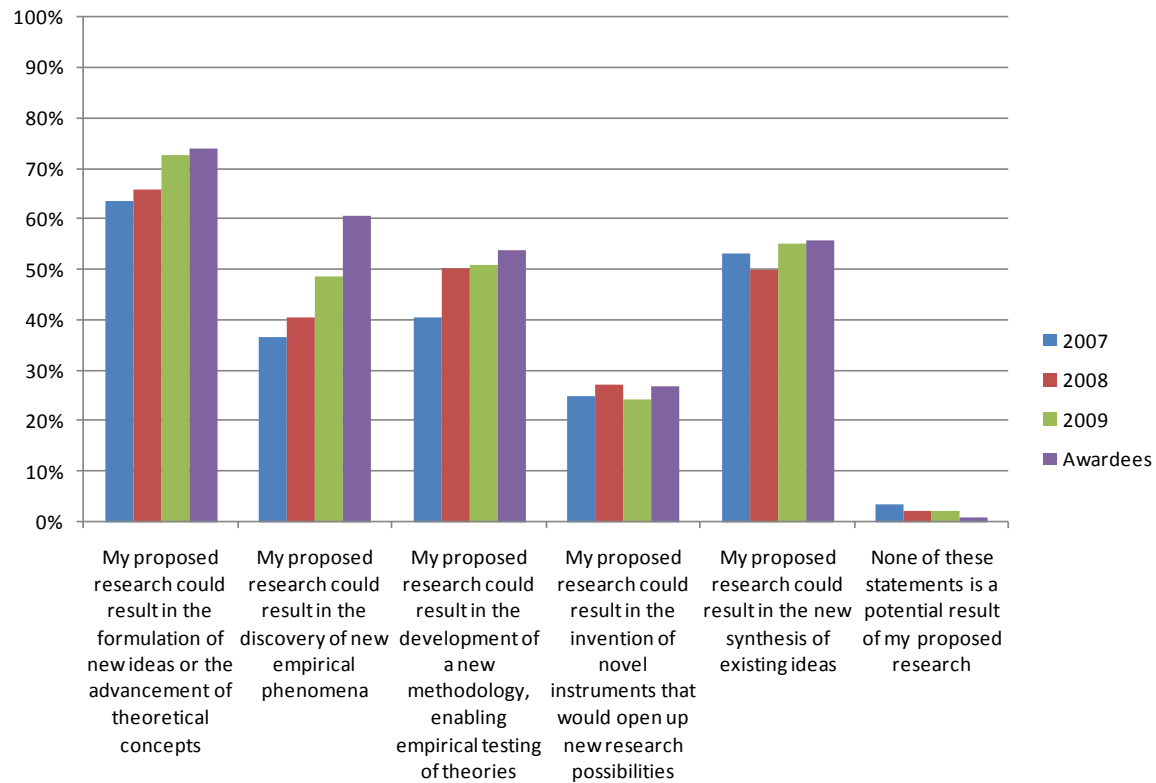

Shown: Applicant responses to a survey question are presented here as the percentage of respondents by year.

Note: The "Colwell Typology" was adapted from a speech by former National Science Foundation Director, Dr. Rita R. Colwell, in which she identified potential metrics for measuring creative research. The speech was accessed from: http://www.nsf.gov/news/speeches/colwell/rc031020lifesci_summit.htm. NIA applicants were asked to characterize their research using the Colwell Typologies and were able to select more than one statement.

Source: NIA Applicant Survey.

Respondents: N=1,627.

Exhibit E-2. Applicant Survey Question: Please indicate which of the following potential outcomes of scientific research apply to your proposed NIA idea in 200X.

Shown: Applicant responses to a survey question are presented here as the percentage of respondents by year.

Note: NIA applicants were asked to characterize their research using the "Heinze Typologies" for identifying creative research accomplishments. The Heinze Typology was adapted from: T. Heinze et al., "Identifying creative research accomplishments: Methodology and results for nanotechnology and human genetics." Scientometrics, Vol. 70, No. 1 (2007) 125–152. Applicants were able to select more than one statement.

Source: NIA Applicant Survey.

Respondents: N=1,628.

Exhibit E-3. Applicant Survey Question: Overall, how satisfied were you with your experience with the NIA program?
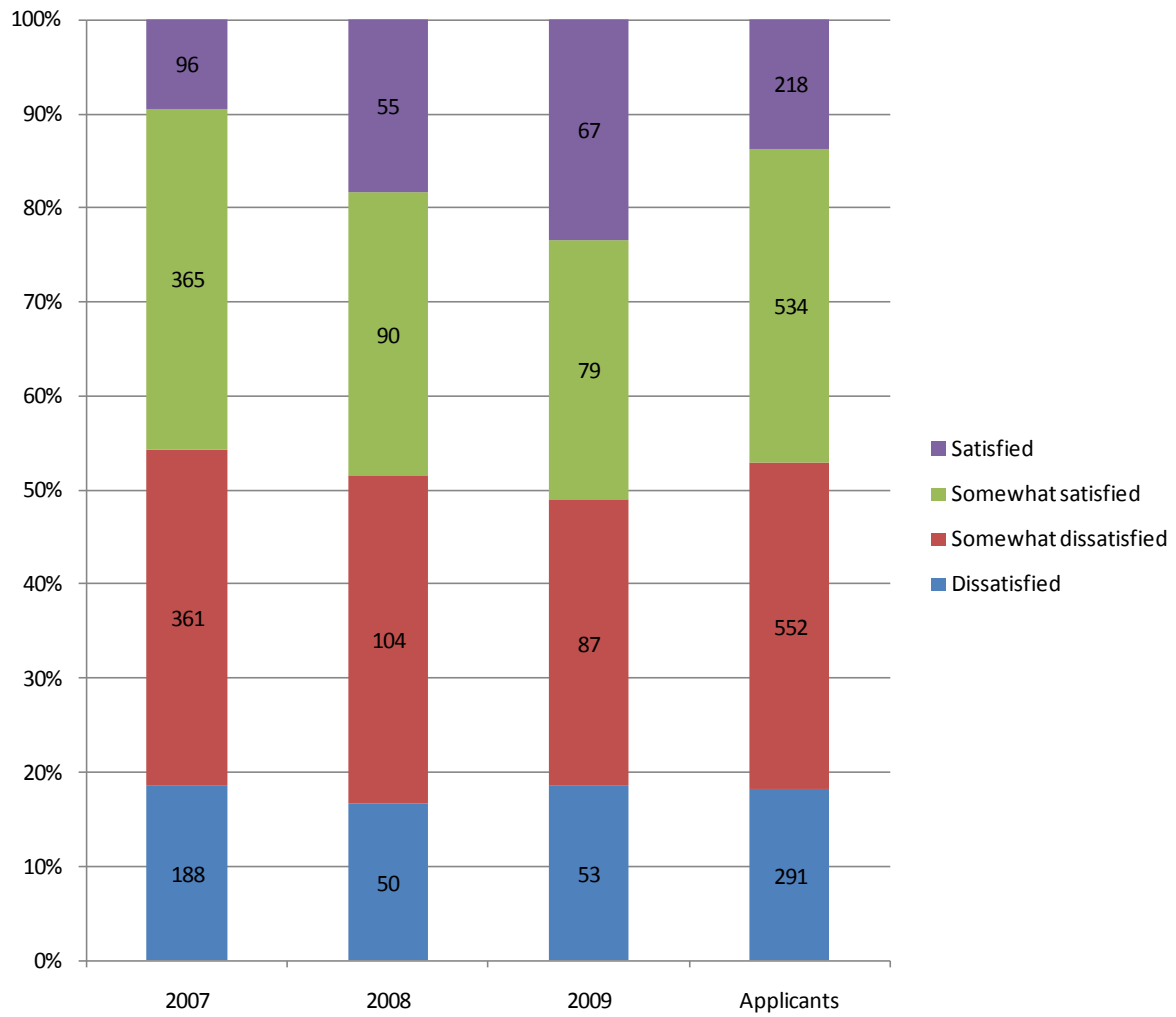
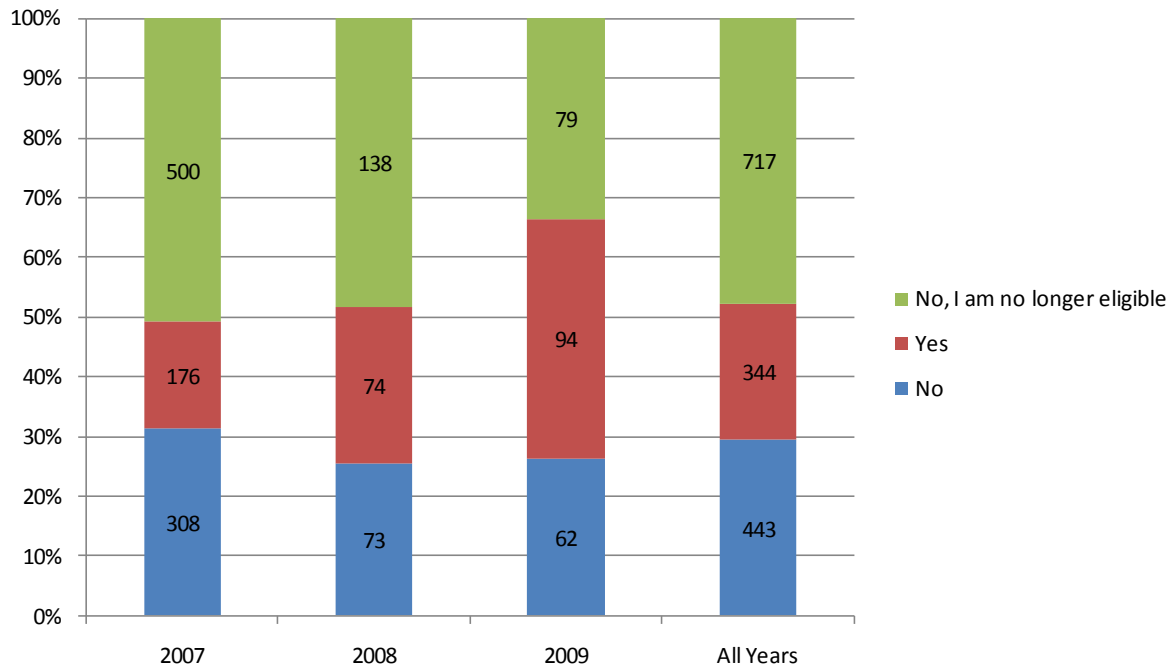|	2007	2008	2009	Applicants
Satisfied	96	55	67	218
Somewhat satisfied	365	90	79	534
Somewhat dissatisfied	361	104	87	552
Dissatisfied	188	50	53	291

Shown: Percent distributions of applicant responses to a survey question.

Source: NIA Applicant Survey.

Respondents: N=1,595.

Exhibit E-4. Applicant Survey Question: Do you plan to reapply to the NIA program?

Shown: Percent distributions of applicant responses to a survey question.
Source: NIA Applicant Survey.
Respondents: N=1,504.

Appendix F. Reviewer Interview Protocol

Attachment 2

II. Extramural Reviewers Informal Discussion Guide

Last Name, First Name:
Title:
Date:
STPI staff:

STATEMENT OF INFORMED CONSENT

The Science and Technology Policy Institute (STPI), a federally funded research and development center based in Washington, DC, has been requested by the National Institutes of Health (NIH) to evaluate the process by which recipients of the **NIH Director's New Innovator Awards (NIA)** were chosen. The primary objectives of the evaluation are to:
  (1) assess the NIA award selection process;
  (2) examine whether the program was implemented as planned; and
  (3) determine if the process was conducted in accordance with the overall mission of the NIA program.

We are employing various data collection techniques to answer these questions; however, we believe that some of the most valuable information will come from those who were involved directly in the evaluation process. These informal interviews are one mechanism that will provide important information concerning the overall NIA process, and will hopefully highlight aspects of the award process that may need to be revised or improved for future rounds of awards. We anticipate conducting approximately 92 such interviews.

Please note that:
- **Your responses will be kept strictly confidential:** If you choose to participate, respondent confidentiality will be protected to the extent provided by law, and STPI will report only aggregate information concerning overall impressions of the process to the NIH.

- **Your participation is entirely voluntary:** You are under no obligation to interview with us, but we strongly encourage you to do so. A successful evaluation of the NIA awards process depends on a high response rate to gather as much information and as many perspectives as possible. There are no consequences or risks for participating. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue the interview at any time without penalty or loss of benefits to which you are otherwise entitled.

- **Whom to contact for additional information:** For additional information about the study you may contact Bhavya Lal, STPI project director (blal@ida.org). If you have any questions that you would like to address to the NIH Office of the Director, please contact G. Stephane Philogene, Ph.D., the Office of the Director's Program Officer responsible for this evaluation (e-mail: PhilogeS@OD.NIH.GOV).

Public reporting burden for this collection of information is estimated to average 30 minutes per interview. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: NIH Project Clearance Officer, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA 0925-0534.

[A] Reviewer Training Process

1. How did you become involved as an NIA reviewer?
   - Do you have an idea of how you were identified as a potential reviewer?
   - Were you involved with the NDPA review process?

2. Do you recall the reviewer training session as part of your participation in the NIA review process?

3. During your training, were the program goals adequately defined and were the review criteria made explicit? Did NIH effectively explain what was meant by "highly innovative," "exceptionally creative," and "potentially high impact?"

4. Do you feel that the training session adequately prepared you for your participation in the application reviews?

5. *(For 2009 Reviewers Only)* Were you made aware of the two phases of review in 2009? Was the purpose of each review phase made clear to you? How did NIH describe the two phases?

[B] Review Process

6. Could you please describe your approach to the review?
   - Did you assign scores for each application individually or did you review all applications before scoring?
   - How did you assign "top 4" designations?

7. Reviewers were instructed to use 3 primary criteria to evaluate individuals: (i) scientific problem to be addressed, (ii) innovativeness of the research, and (iii) investigator qualifications. Can you please give an example of how you applied each of the criteria?
   - Which of the review criteria was most important to you in your assessment of the applications?
   - How did you use each of the elements in the application materials to help your review?
   - How did you apply the 1-5 scoring scale for each of the criteria and assign the "overall" score?
   - What specific characteristics were you looking for in the applications?

- How did you apply terms like "innovativeness," "exceptional creativity," "high impact"?
- Do you believe these criteria are adequate to achieve the NIA's goals? If not, what other criteria might be used in the future years?

8. How did you evaluate applications outside of your area of expertise?
   - Were there instances where you relied on reference material to inform your review?
   - Were there instances where you were not comfortable with reviewing an application because of the subject area?

9. Were you given sufficient time to review the applications?

[C] Scoring System

10. Were the scoring scale (1-5) and the "top 4" designation adequate to rate the applications? If not, what suggestions do you have for improving the scoring?

11. *(07 evaluators only)* Were the standardized comments used in 2007 the best way to give feedback to applicants? Would you recommend that NIA use this method in the future? If no, why not?

12. Did you use the option of providing short comments on the applications? Any suggestions or feedback regarding the commenting feature?

13. Did you feel comfortable scoring the applications independently and outside of a convened session? *(Prior to the conference call—for Phase II reviewers)*
    - Would you prefer to be given feedback on your review?

[D] 2009 Phase II Review *(Phase II Reviewers only)*

14. Do you recall participating in the conference call to discuss the final rankings?

15. What materials did you receive prior to the teleconference (e.g. applications or comments of other reviewers on the applications)?

- How did you prepare for the conference call?
  - Did you review the materials you received prior to the call?

16. Can you walk me through the discussion of the applications during the teleconference?
    - Who led the call?
    - Can you describe the interactions between reviewers during the call?

17. Were you satisfied with the tiered ranking of the applications?
    - Were there any cases where applicants' rankings were changed?
      - What were the reasons for these changes?

18. Was discussing the applications with the other reviewers useful for finalizing the ranking?

19. How, if at all, did the discussion change your view of the applications you had previously reviewed independently?
    - Do you believe that the program should consider utilizing this component of the review in future years? If not, why not?
    - Any other suggestions regarding this component for future years?

[E] General Characterization

20. How would you characterize the applications you reviewed in terms of creativity and innovation?
    - Have you served on a NIH study section?
      - Based on the applications you reviewed, how did they compare with applications you have seen for other NIH mechanisms, e.g. R01, R21s?

21. Have you seen a list of the awardees, or are you familiar with who was awarded?
    - Would you have liked to have received a list of the awardees from the NIA program staff?

22. *(If they have been an evaluator for NDPA)* How do the ideas proposed for NIA differ from those proposed for NDPA?
    - Does NIA serve a different purpose from the NDPA? Or could the NDPA just designate a percentage of the awards to go to early career researchers?

STPI DRAFT—DO NOT CITE OR DISSEMINATE

- Did the proposals you reviewed meet your expectations, given the goals of the NIA program?

23. In your opinion, did NIA truly capture researchers and/or ideas that otherwise would not be in the NIH system?
    - Or do you think with more time and data, the person and/or the idea would eventually be funded by NIH and the NIA just accelerates the process?

24. To the best of your knowledge, to what extent, if any, is NIA adding value to the NIH portfolio?
    - Is there evidence of spillover effects of the award? For example, do you think the culture at NIH or the perception of NIH has changed as a result of the NIA?

25. *(Repeat Evaluators Only)* In your opinion, how did the 2009 review process compare to that of previous years? How did the applicants and proposals compare?

26. Given your experience as a reviewer, would you consider being involved in the program again in the future? If not, what must change for you to participate again?

27. Do you have any additional feedback on the FY 200X NIA process? Do you think the selection process design or implementation should change? Do you have any other recommendations for how the program could be improved?

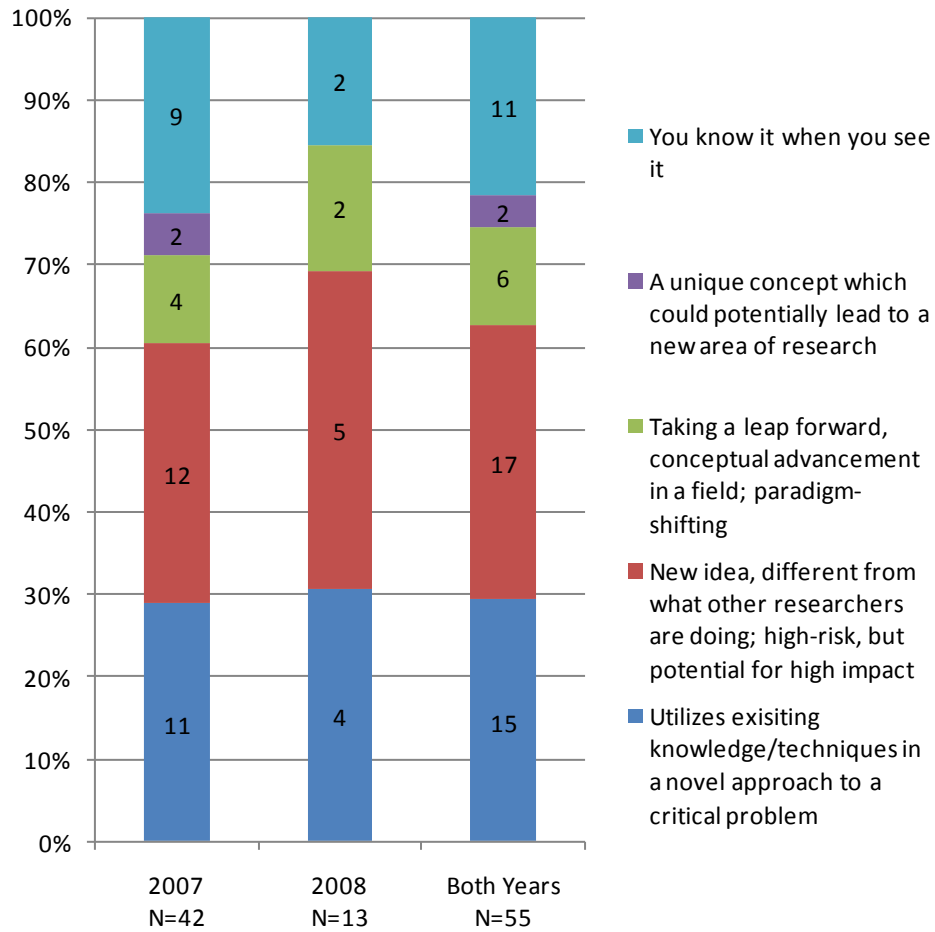# Appendix G. Additional Reviewer Interview Responses

Exhibit G-1. Reviewer Interview Question: In your opinion, did NIH truly capture researchers and/or ideas that otherwise wouldn't be in the NIH system?
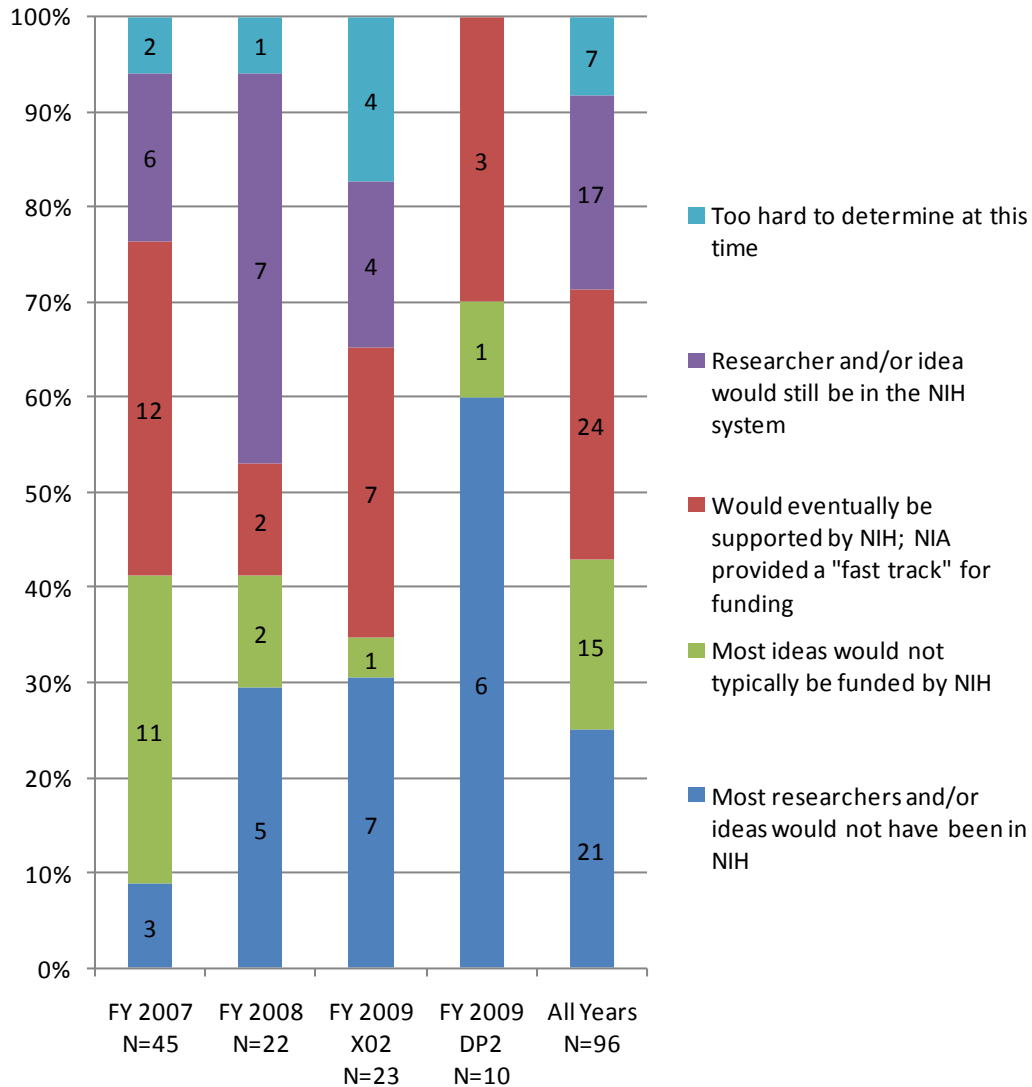
Source: NIA Reviewer Interviews.

Shown: Percent distributions of reviewers' responses to an interview question.

Exhibit G-2. Reviewer Interview Question: How do you define innovation?

Legend:
- **You know it when you see it**
- **A unique concept which could potentially lead to a new area of research**
- **Taking a leap forward, conceptual advancement in a field; paradigm-shifting**
- **New idea, different from what other researchers are doing; high-risk, but potential for high impact**
- **Utilizes exisiting knowledge/techniques in a novel approach to a critical problem**

	2007 N=42	2008 N=13	Both Years N=55
You know it when you see it	9	2	11
A unique concept	2		2
Taking a leap forward	4	2	6
New idea	12	5	17
Utilizes existing knowledge	11	4	15

Source: NIA Reviewer Interviews.

Shown: Percent distributions of reviewers' responses to an interview question.

Note: This question was only asked of FY 2007–2008 reviewers.