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Report to the Chairman, Committee on Labor and Human Resources, U.S. Senate

February 1989

AIDS RESEARCH

NIH Review Process and Outcome of Applications for Grants and Contracts

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United States
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Human Resources Division

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February 3, 1989

The Honorable Edward M. Kennedy
Chairman, Committee on Labor and
Human Resources
United States Senate

Dear Mr. Chairman:

In response to your request, we have examined the process followed by the National Institutes of Health to review and fund grant and contract applications for AIDS research and the outcome of applications submitted for funding in fiscal year 1986. This report contains the results of our review.

Copies of the report are being sent to the appropriate congressional committees, the Secretary of Health and Human Services, the Director of the Office of Management and Budget, and other interested parties.

The major contributors to this report are listed in appendix IV.

Sincerely yours,

Lawrence H. Thompson

Lawrence H. Thompson
Assistant Comptroller General

Executive Summary

Purpose

With more than 108,000 cases reported worldwide as of July 1988, Acquired Immune Deficiency Syndrome (AIDS) has become of global concern. There is no known cure for AIDS, nor is there a vaccine to prevent the spread of the virus that causes it. It is the number one health priority of the Public Health Service. The Congress has provided the National Institutes of Health (NIH) with almost a billion dollars during fiscal years 1982-88 for research on this disease.

The Chairman of the Senate Committee on Labor and Human Resources expressed interest in the NIH process for awarding AIDS research grants and contracts for fiscal year 1986. He asked whether established procedures were followed and whether they encouraged participation by all responsible segments of the research community.

For principal investigators who had AIDS research applications funded, approved but not funded, and disapproved during fiscal year 1986, GAO agreed to prepare profiles. These included experience, age, sex, prior service on an NIH review committee, previous grant and contract awards, affiliation with one of the 20 organizations receiving the most NIH research funds, and academic degree earned.

Background

As of July 1988, the Centers for Disease Control reported over 69,000 cases of AIDS in the United States and almost 39,000 known deaths since 1981. Expenditures for AIDS research by NIH, the principal biomedical research arm of the Department of Health and Human Services, have grown dramatically. From $3.4 million in fiscal year 1982, they increased to $260.9 million in fiscal year 1987 and an estimated $467.8 million in fiscal year 1988. While all NIH institutes support research on AIDS through internal studies or studies funded by grants and contracts, three have accounted for almost 90 percent of NIH AIDS funding. These are the National Cancer Institute, the National Heart, Lung, and Blood Institute, and the National Institute of Allergy and Infectious Diseases.

NIH receives both solicited (NIH-initiated) and unsolicited (investigator-initiated) grant applications. To determine which are worthy of funding, NIH uses a "dual review system." All applications are reviewed for scientific merit—first by scientists who are engaged in research but not associated with the proposal and second by each institute's statutorily mandated national advisory council or board comprised of scientific, medical, and public representatives. This process results in all applications being numerically scored and ranked based on their scientific merit.

Results in Brief

The NIH process for reviewing and awarding extramural grants and contracts appears adequate to encourage participation by all responsible segments of the research community and to help ensure that high priority needs of the institutes are addressed.

Expertise in the research area of the work proposed and, for contract applicants, association with one of the 20 organizations that received the largest amounts of NIH research funds in the preceding year, appeared to be the most important predictors of who would receive funding. For other characteristics—age, sex, experience on an NIH review panel, prior NIH funding, and type of doctoral degree—there was less correlation. Young researchers (those 40 and under) were funded at a slightly higher rate for both grants and contracts than those 41 and over.

Principal Findings

Some Variations in Grant Review Process Found

At the three institutes GAO reviewed, solicited grant applications for AIDS research were funded in accordance with the established NIH procedures. For unsolicited applications, however, the three institutes had varying procedures for determining which to fund. NIH allowed these variations, requiring written justification, to better meet program needs or address mandated areas of research.

Contracts were used by NIH to fund an NIH-directed scientific project with a well-defined statement of work. After development and peer review of a project concept, an institute would issue a request for proposal. Contract proposals responding to the request underwent an initial review and technical evaluation by independent peer reviewers.

Secondary Review for Contract Proposals Differed

The three institutes' procedures differed in terms of who served on their secondary review groups (see p. 18) and the point at which the groups became involved in the review process.

- The National Cancer Institute used a secondary review group to recommend which proposals to include in the competitive range.
- The National Institute of Allergy and Infectious Diseases used such a group after determination of competitive ranges, to assist the contracting officer in determining which proposals to fund.

- The National Heart, Lung, and Blood Institute, however, permitted its secondary review groups to rescore contract proposals prior to the determination of competitive ranges. This could and in one case did change which offerers were deemed competitive. But in August 1988 the institute changed this process to require approval of the rescoring by the chief of the institute's Contract Operations Branch. Prior to that time, approval was by lower level officials. (See pp. 17-19.)

Expedited Review Begun

In May 1988, NIH began using an expedited review process for funding AIDS research. AIDS grant applications and contract proposals now are segregated from all others, and the review process is begun earlier in the funding cycle. The expedited process is expected to take 6 months from receipt of an application or proposal until funds are awarded in comparison with a 10- to 11-month period for AIDS research applications processed in fiscal year 1986 and for non-AIDS research applications. (See pp. 19-20.)

NIH Efforts to Assist Potential Applicants

NIH assists potential applicants for NIH research funds in several ways. Health science advisors at each institute notify applicants of the results of peer reviews and discuss any problems with applications. Also, potential applicants may contact the advisors to discuss proposed research and seek suggestions for revisions. The science advisors attend numerous scientific conferences where they meet grant applicants and discuss proposed research. Although contracting regulations restrict contacts between NIH personnel and contract applicants, potential contract applicants can attend four or five regional meetings NIH sponsors each year to provide assistance to the research community. (See p. 20.)

Expertise, Prior Participation Major Factors Affecting Funding Success

At the three institutes reviewed, GAO sought to judge the relevant expertise of the investigators involved in applying for AIDS grants and contracts in fiscal year 1986. To do so, GAO asked the assistance of three NIH officials having scientific backgrounds but not involved in the award process and unaware of funding outcomes. Using a scale of 0 to 5 with 5 being the highest, the officials independently rated applicants' relative expertise to perform the proposed work. Of grant applicants rated 4 or 5, 39 percent were funded, but only 15 percent of those with scores of 0 to 3 were funded. For contracts, 52 percent of applicants rated 4 or 5 and 29 percent of those rated 0 to 3 were funded. (See pp. 22-24.)

With respect to the other researcher characteristics examined, GAO found the following:

- Applicants aged 40 or under had a slightly higher success rate for both grants and contracts than those 41 and over. Individual awards were, however, higher on average for the older investigators. (See pp. 24-25.)
- Male and female applicants for AIDS grants were funded at the same rate. For contracts, males were funded at a higher rate (41 percent versus 30 percent). (See pp. 25-26.)
- Those who had previously served on an NIH chartered review committee were funded at a higher rate than those who had not. (See pp. 26-27.)
- Applicants who had been prior recipients of NIH grants or contracts did better than those who had not received prior awards. (See pp. 27-28.)
- Grant applicants currently associated with the 20 organizations that had received the largest amounts of NIH funds the previous year were funded at the same rate as those that were not. In contrast, 62 percent of contract applicants from the 20 largest recipients of NIH funds were funded, while 35 percent of contract applicants from all other organizations were funded. (See pp. 28-30.)
- Most principal investigators applying for AIDS funding held MD or PhD degrees. PhDs had the higher funding rate for grants, but also the highest application disapproval rate. For contracts, MDs had the higher funding rate but about the same disapproval rate as PhDs. (See pp. 30-31.)

Recommendations

This report contains no recommendations.

Agency Comments

GAO did not obtain formal agency comments on this report. However, GAO did discuss the information in the report with NIH officials. Their comments have been incorporated in the report, as appropriate.

Contents

Figures

Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
CR	contract competitive range
DRG	Division of Research Grants
FIRST	First Independent Research Support and Transition
GAO	General Accounting Office
IRG	initial review group
MD	Doctor of Medicine
NCI	National Cancer Institute
NHLBI	National Heart, Lung, and Blood Institute
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
PhD	Doctor of Philosophy
PS	grant priority score
RFA	request for application
RFP	request for proposal

Introduction

Acquired Immune Deficiency Syndrome (AIDS) is a disease that impairs the immune system and leaves affected individuals susceptible to certain types of cancer and a number of infections. There is no known cure for AIDS, nor is there a vaccine to prevent the spread of the human immunodeficiency virus that causes it. The U.S. Surgeon General has reported that AIDS is spread not by casual social contact, but primarily through intimate sexual contact and the sharing of hypodermic needles and syringes by intravenous drug users. In addition, infected pregnant women can transmit the disease to their unborn child. AIDS also can be spread via contaminated blood to persons receiving transfusions. Since 1985, however, blood donations have been screened for the presence of the AIDS virus.

With more than 108,000 cases reported to the World Health Organization as of July 1988, AIDS has become of global concern. Between 5 and 10 million persons are infected with the human immunodeficiency virus, the organization estimates. As of July 1988, over 69,000 cases of AIDS and almost 39,000 known deaths had been reported by the Centers for Disease Control in the United States since 1981. The Centers estimates that 1 to 1.5 million Americans are infected with the human immunodeficiency virus. AIDS is the number one health priority of the Public Health Service.

By the end of 1991, the total number of AIDS cases in the United States will exceed 270,000, with more than 179,000 deaths, according to a 1986 projection by the Public Health Service. Nationwide, the costs of providing medical care to persons with AIDS are expected to increase from $1.1 billion in 1985 to $8.5 billion in 1991. Total costs to the nation—personal medical care and services, lost income, decreased consumption, and insurance payouts—are expected to increase from $8.7 billion in 1986 to about $66.5 billion in 1991. Worldwide, 50-100 million people will be infected with the virus by 1991, according to the World Health Organization.

Role of the National Institutes of Health

The National Institutes of Health (NIH) is the principal biomedical research arm of the Department of Health and Human Services. NIH is composed of 13 research institutes, the Division of Research Resources, 3 service divisions, a research hospital, the National Library of Medicine, and the Fogarty International Center. All NIH research components support research on AIDS through intramural studies and/or extramural programs with outside research organizations (universities, medical schools, etc.) funded by grants and contracts. During fiscal

years 1982-88, the Congress provided NIH with almost a billion dollars for research on this disease.

NIH expenditures for AIDS research, both intramural and extramural, increased from $3.4 million to $260.9 million between fiscal years 1982 and 1987. An estimated $467.8 million will be spent in fiscal year 1988, and $587.6 million has been requested for fiscal year 1989. The primary institutes involved in AIDS research, both intramural and extramural, are the National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute (NHLBI), and the National Institute of Allergy and Infectious Diseases (NIAID). These three accounted for almost 90 percent of the NIH AIDS funding for fiscal years 1982-87.

In fiscal year 1986, NIH spent $134.7 million for AIDS research. This report focuses primarily on applications submitted for competitive grants and contracts awarded that year. Table 1.1 shows the total spent on intramural and extramural research by the three institutes we reviewed and other NIH institutes.

Table 1.1: NIH Funding for AIDS Research (Fiscal Year 1986)

Figures in thousands

	AIDS research funds	
Institute	**Intramural**	**Extramural[a]**
NCI	$13,550	$31,500
NHLBI	0	15,468
NIAID	10,960	52,316
All others	2,604	8,269[b]
Totals	**$27,114**	**$107,553[b]**

[a]Includes the research management support appropriation, which funds administration of the AIDS program and relates primarily to the management of the extramural program.

[b]Includes $73,000 for the Office of the Director, NIH, for overall direction of the AIDS program.

A total of 163 organizations received financial support from NIH in fiscal year 1986 for AIDS work. The recipients of AIDS grants and contracts awarded by NIH that year came from 34 states, the District of Columbia, and 5 foreign countries.

Objectives, Scope, and Methodology

In July 1987, the Chairman of the Senate Committee on Labor and Human Resources expressed interest in whether the NIH process for distributing AIDS grant and contract funds to researchers was adequate to ensure an appropriate "mix" between long-established and younger researchers. The Chairman was concerned that NIH may be providing

funds to established research organizations and not recognizing innovative research being conducted by others. His concerns also encompassed the organizational and administrative structure NIH used in making spending decisions for fiscal year 1986 AIDS research. Accordingly, he asked us to

- review NIH criteria and procedures for awarding grants and contracts for extramural research on AIDS and determine whether the procedures were followed for awards made in fiscal year 1986 and
- compile profiles of the principal investigators who applied for fiscal year 1986 grants and contracts for AIDS research and were approved and funded, approved but not funded, and disapproved. These profiles were to include experience, age, sex, service on NIH review committees, previous NIH grant and contract awards, affiliation with a top 20 NIH research organization,[1] and academic degree earned.

Because the requester sought information on the grant and contract review and award procedures followed in fiscal year 1986, we examined only that year's applications competing for AIDS research funds. We reviewed competing contract and grant applications for traditional research project grants, new investigator research grants, outstanding investigator awards, and small business innovation research grants.[2] Grants and contracts generally are awarded on a multiyear basis.

Focusing our review on initial awards, we did not examine applications for noncompeting continuations, extensions, supplements, or contracts awarded on a sole-source basis. These applications were not subject to peer review during fiscal year 1986.[3] As agreed with the requestor, we did not review grant applications that were not directly research-oriented or that involved multiple principal investigators because no single investigator had primary responsibility for the proposed research.

From NIH, we obtained computerized lists of all NCI, NHLBI, and NIAID grant and contract applications considered for fiscal year 1986 funds for AIDS research. We selected for review the 280 grant and contract applications submitted to the three institutes for 1986 funding that met the

[1]Defined as among the top 20 research organizations in receiving NIH grants and contracts during the previous fiscal year.

[2]These grants to small business firms support projects to establish the technical merit, feasibility, and development of research ideas that are likely to result in commercial products or services.

[3]These noncompeting continuations, extensions, and supplements would have been initially awarded on a competing basis in a prior year.

above-stated criteria. During fiscal year 1986 and throughout the period 1982-87, these three institutes spent approximately 90 percent of all the funds spent by NIH on AIDS research. The number of grant and contract applications we examined is shown by institute in table 1.2. Of the applications we examined, 39 grants and 51 contracts were approved and funded, with first-year costs totaling $5.4 million and $34.9 million, respectively.

Table 1.2: Applications Examined by GAO

Institute	No. of applications	
	Grants	Contracts
NCI	38	51
NHLBI	7	22
NIAID	107	55
Totals	**152**	**128**

To determine NIH's procedures for reviewing and approving applications and making funding decisions for grants and contracts, we conducted interviews and reviewed written policy and procedure statements, both NIH-wide and institute-specific. We interviewed officials in NIH's Office of Administration and Office of Extramural Research and Training and the Division of Research Grants' Office of the Director; the Referral and Review Branch and Statistics and Analysis Branch within the Division; and the executive secretary of one initial review group (IRG).[4] For each of the three selected institutes, we interviewed the executive officer, financial/budget officer, director of extramural activities, and other program staff.

We reviewed the documentation in the files for all 280 competing contract and grant applications to determine whether NIH's procedures were followed. To determine the characteristics of each principal investigator who applied for a grant or contract in fiscal year 1986, we designed a data collection instrument to help assure the consistent collection of data from each file. The specific methodology we used to determine these characteristics is described in appendix III.

[4]To determine the scientific merit of research grant applications and contract proposals, NIH uses a system of peer review groups acting independently of NIH. As of August 1988, there were over 100 of these groups. Most grant application peer review groups are administratively managed by the Division of Research Grants where they are referred to as initial review groups. Other peer review groups for the review of contract proposals and some grant applications are administratively managed by the individual NIH institutes.

To distinguish between a young and an established researcher, we selected 40 as the "age cutoff." The choice was based on discussions with and the recommendation of the Deputy Director for Extramural Research and Training, NIH. The Deputy Director believes this age allows sufficient time to obtain advanced degrees and minimal experience needed to become a principal investigator.

Although we did not validate NIH's computerized information system from which we identified all AIDS applications submitted, we did obtain the perceptions of NIH program officials as to the accuracy of the system and the data in it. Generally, these officials believe that the NIH information system provides accurate and complete historical data about grant and contract applications. We observed the process by which initial information from applications are entered into the system. We have no reason to believe data derived from this system is inaccurate to an extent it would invalidate our audit results.

Our work, done from July 1987 through May 1988, was conducted in accordance with generally accepted government auditing standards.

NIH Process for Awarding Grants and Contracts for AIDS Research

The process for reviewing and funding AIDS grant applications and contract proposals followed by NCI, NIAID, and NHLBI in fiscal year 1986 appeared adequate to encourage participation by all responsible researchers and to ensure funding of high-priority program needs. NIH allows each institute flexibility in adopting alternative procedures to help ensure that high priority program needs can be met. For grant applications, the three institutes had varying procedures for determining which approved, unsolicited (investigator-initiated) applications would be funded. For contracts, the institutes used different procedures related to the membership of secondary review groups (see p. 18) and when these groups became involved in the review process.

NIH has a special mechanism under which new researchers can apply for grants. In addition, it assists potential applicants for grants and contracts by providing direct advice and holding regional meetings to explain the NIH grant and contract process.

Review and Funding of Grant Applications

For grant applications, NIH used an external "dual review system." Both unsolicited and solicited applications received an initial review for scientific merit by scientists actively engaged in research. There was then a second review by a statutorily mandated national advisory council or board comprised of scientific, medical, and public representatives. This system provided an objective evaluation of each application's scientific and technical merit separate from an institute's spending decisions, which were based on its programs and priorities.

Briefly, the application review and funding process for AIDS research grant applications was as follows:

- Unsolicited applications were submitted to NIH on the initiative of a principal investigator, and solicited applications were submitted on the basis of a request for applications (RFA) issued by an NIH institute.
- Members of an initial review group (generally not federal employees, but scientists actively engaged in research in the private sector) reviewed the application and voted to approve, disapprove, or defer it. Approved applications were given a priority score based on scientific merit, ranging from 100 to 500 (100 being the best). The applicants received summaries of the IRG action on each application.
- The national advisory council or board of the cognizant institute concerned also reviewed the applications and usually concurred with the

IRG's recommendations. While the board or council could revise the recommendations or return an application to the IRG for further review, it could not change the priority score.

- Each institute normally funded the applications recommended for approval using the initial review group's priority score. It funded those above a predetermined "payline" or cutoff until it had obligated all available funds. Funding decisions were not subject to appeal.

In reviewing applications for fiscal year 1986 competitive grants, the three institutes that primarily fund AIDS research—NCI, NHLBI, and NIAID—utilized this two-level, external peer-review process. We found no instances where they departed from the NIH process for reviewing and funding solicited grant applications. However, for unsolicited applications, the institutes varied somewhat in their funding procedures, as follows:

- NCI set a new payline score for each funding cycle but if it believed program objectives were not being met, its procedures provided for skipping (not funding) some applications above the payline in order to fund others below the payline.
- NHLBI made its funding decisions by ranking approved applications using a percentile system (see p. 34-35).
- NIAID funded applications scoring above a payline set at the start of a fiscal year. Its procedures also provided for funding on a selective basis some applications below the payline. Such selective funding was done on request from its program offices in order to address program needs or mandated research areas.

More details on this process, which was still being used as of November 1988, are provided in appendix I.

Special Funding Mechanism to Assist New Investigators

NIH has a special funding mechanism under which new principal investigators can apply for grants. The mechanism used in fiscal year 1986 was the New Investigator Research award. Its purpose was to support basic research and clinical studies for newly trained investigators. In August 1986, a successor to this award mechanism, the First Independent Research Support and Transition (FIRST) award, was initiated. It aims to give newly independent biomedical investigators a sufficient period of research support to initiate and demonstrate the merit of their research ideas.

In fiscal year 1986, NIH received a total of 973 applications for the New Investigator and FIRST awards. Of these, 923 (95 percent) were recommended for funding consideration by the IRGs and institute advisory councils or boards. Funds were awarded to 353 (38 percent) of the approved applications.

The combined approval and award rates for the New Investigator Research awards and the FIRST awards were slightly higher than the rates for traditional research projects in fiscal year 1986. That year, NIH received 15,500 applications for competing traditional research projects, of which 14,470 or 93 percent were recommended for funding consideration. There were 34 approved applications carried over from the previous fiscal year, resulting in 14,504 eligible applications. Of these, 4,931 (34 percent) were funded compared with the combined 38 percent of the eligible New Investigator Research and FIRST awards.

NIH awarded $19.3 million for New Investigator Research and FIRST grants in fiscal year 1986. This increased to $85 million in fiscal year 1987. For AIDS work in fiscal year 1986, four New Investigator Research grants totaling $182,758 were awarded but no FIRST awards. In fiscal year 1987, 13 New Investigator Research and FIRST grants totaling $1,014,515 were awarded for AIDS work. This was more than five times the amount awarded in fiscal year 1986.

Contract Proposal Review and Award Process

After developing a concept for the investigation or performance of a scientific project and obtaining a scientific peer review of the concept, an institute then issued a request for proposal (RFP). Proposals responding to the RFP underwent an initial scientific review and technical evaluation by independent peer reviewers and, after negotiation and revisions, a second or final review.

Thus, proposals for contract funds for AIDS research generally were subject to the following process:

- The proposals were referred to an external peer review group.
- The review group rated and scored the proposals according to evaluation criteria identified in the RFP.
- The contracting officer determined which proposals were in the competitive range and notified all offerers of the peer review results.
- After negotiating the technical and business aspects of their proposals with the institute, offerers in the competitive range submitted best and final offers.

- The contracting officer and project officer, sometimes assisted by a second review group and others, reviewed the final offers and sometimes rescored them. Aided by these results, the contracting officer selected the contracts to be awarded and sent them to institute management for concurrence.

NIH allowed its institutes to vary this process. The three institutes whose AIDS research activities we examined varied their process as to who served on secondary review groups and where in the process the groups became involved, as follows:

- NCI used a "source evaluation group," composed of federal experts, to review the peer group's rankings and recommend which proposals to include in the competitive range. Later, the evaluation group reconvened to review and sometimes rescore the final offers. The contracting officer made the final selection.
- NHLBI used a secondary review group to help the contracting officer establish the competitive range. This group, comprised of program staff and sometimes outside experts, was permitted to rescore the proposals before the competitive range was set. Rescoring had to be documented and had to be approved by section heads within the NHLBI Contracts Operations Branch. The contracting officer then determined the competitive range. Such rescoring could change which proposals were included in or excluded from the competitive range. An offerer excluded in this manner would not be given an opportunity to respond to reviewers' questions and submit a best and final offer, as were those who were ultimately determined to be in the competitive range. This occurred for one contract proposal included in our review.

  After we discussed the rescoring of proposals with NIH and NHLBI officials, we were informed by an NHLBI official that NHLBI was changing the process to require the chief of its Contracts Operations Branch to approve the justification for rescoring proposals.

- NIAID's Chief, Contracts Management Branch, and the contracting officer determined the competitive range after considering peer review group rankings and program staff advice. A "source selection committee," including peer reviewers, project staff, and an extramural program official, reviewed best and final offers and could rescore them. Their recommendations guided the contracting officer in final selections, which required approval by NIAID management.

This process, which was still being used as of November 1988, is described in greater detail in appendix II.

Expedited Review Process for AIDS Grant and Contract Applications

During the period of our review, NIH established an expedited process of referral, review, and award for all grant applications (unsolicited and solicited) and contract proposals for AIDS research. NIH estimates the new process will take about 6 months from receipt of an application to the time an award is made, compared with 10 or 11 months for the process used for fiscal year 1986 grants and contracts and still used for non-AIDS research applications.

For grants, NIH set new due dates for receipt of applications. AIDS applications arriving on or before the new dates are to receive an expedited review. The first group of applications so handled was received on May 1, 1988. It is up to the applicant to decide whether to submit an application for review under the expedited process or the regular review process. If the latter is chosen, the submission undergoes the usual referral process and is assigned to the most appropriate IRG.

To be included in the expedited process, an application must be directly applicable to AIDS, have "AIDS research" marked on it, and be sent to an NIH address specifically for AIDS applications. The applications are reviewed by initial review groups whose members are experts in various disciplines related to AIDS and by the institutes' national advisory councils or boards.

The expedited process for solicited applications differs from that for unsolicited applications in two respects:

- Prospective applicants may be asked to send letters indicating their intent to submit applications. This facilitates early formation of IRGs and (when necessary) arrangements for site visits.
- "Triage," an initial screening by a scientific peer review group to eliminate noncompetitive applications from further consideration, may be used. Under triage, applications submitted in response to a particular RFA are divided into two categories: noncompetitive and competitive. Applications determined to be competitive then go through the normal IRG process. NIH considers triage useful when large numbers of responses or modest numbers of more complex applications are expected. The RFA indicates the possibility that triage may be used and describes the

sequence of review procedures. It also specifies procedures for applications received late, incomplete, eliminated by triage as noncompetitive, or deemed not to address the RFA's intent.

Under the new process for contracts, NIH expects awards to be made 6 months after the proposals responding to an RFP are received. To facilitate early formation of the peer review group, prospective offerers are asked to submit letters of intent to submit proposals. The new process is intended to minimize intervals between steps of the review process and expedite special clearances as necessary. According to an NIH official, the "triage" procedures are not used for contract proposals because doing so would violate existing government procurement regulations.

NIH Efforts to Assist Potential Applicants

NIH has several mechanisms by which potential grant and contract applicants can receive assistance. Each NIH institute has health science advisors, according to the Deputy Director of the Division of Extramural Research. These advisors notify applicants of the results of peer review and often suggest that applicants call to discuss any problems with applications. Also, potential applicants may contact the advisors to discuss their proposed research and seek suggestions for revisions. Finally, the science advisors attend numerous scientific conferences where they meet grant applicants and discuss proposed research.

The Deputy Director told us that contracting regulations require that contacts between NIH personnel and contract applicants be in accordance with prescribed government contracting procedures. But whether contract- or grant-oriented, potential applicants can attend four or five regional meetings NIH sponsors each year. At these meetings, NIH personnel discuss the grant application and contract proposal review process, common problems encountered, and possible solutions.

Conclusions

The process followed by NIH institutes for reviewing and awarding extramural AIDS grants and contracts separates the assessment of scientific and technical merit of applications from an institute's spending decisions, which are based on its programs and priorities. This appears to us to provide an objective evaluation of each application. At the same time, it permits the institutes to select some proposals that do not rank as high as others to meet their program objectives and research priorities.

The procedures adopted by NHLBI for reviewing AIDS contracts allowed rescoring of proposals by secondary review groups, which had the potential to, and in one case we reviewed did, change the proposals that were deemed to be competitive. In August 1988, however, NHLBI changed its procedures for future contracts so that the justification for such rescoring would have to be approved by the chief of the institute's Contract Operations Branch.

Analysis of Applicants for AIDS Funding Based on Selected Characteristics

Expertise in a particular field of research work was a significant characteristic of AIDS researchers who received grant or contract awards from NIH in fiscal year 1986. Also, contract applicants associated with the top 20 organizations receiving prior NIH funding did considerably better than those associated with other organizations. These two applicant characteristics were the only ones we analyzed that showed a strong correlation with funding success. For the others—age, sex, prior experience on an NIH review panel, prior NIH funding, and type of doctoral degree—there was only weak correlation or none.

Highlights of Analyses

We found the following:

- Applicants with the highest ratings in relevant expertise were funded at a significantly higher rate for both grants and contracts than applicants with the lowest ratings. (See pp. 22-24.)
- Applicants aged 40 or under were funded at a higher rate for both grants and contracts than those 41 and over. (See pp. 24-25.)
- Male and female applicants for grants were funded at the same rate. For contracts, males were funded at a higher rate. (See pp. 25-26.)
- Those who had previously served on an NIH-chartered review committee were funded at a higher rate than those who had not served on such committees. (See pp. 26-27.)
- Applicants who had been prior recipients of NIH grants or contracts did better than those who had not received prior awards. (See pp. 27-28.)
- Grant applicants currently associated with the 20 organizations that had received the largest amount of NIH funds the previous year were no more likely to be funded than those that were not, but contract applicants thus connected were significantly more likely to be funded. Of contract applicants from the 20 largest recipients of NIH funds, 62 percent were funded, while 35 percent of contract applicants from all other organizations were funded. (See pp. 28-30.)
- Most principal investigators applying for AIDS funding held MD or PhD degrees. Grant applications from PhDs were funded at a higher rate than those from MDs but also had a higher percentage of grant applications disapproved than MDs. For contracts, MDs had the higher funding rate and had about the same unacceptable rate as PhDs. (See pp. 30-31.)

Relevant Expertise of Principal Investigators

Relevant expertise to perform the tasks specified in the grant and contract proposals appears to be the factor that made the biggest difference in grant and contract applicants' chances of being funded (see table

3.1).[1] For the applications examined, we analyzed this factor by asking the help of three NIH officials with science backgrounds. They independently reviewed the proposed statements of work and the applicants' experience statements or curriculum vitae (included in the application packages). These included information about the applicants' education, experience, and publication histories. The officials, who were not told which applications were funded, rated each applicant's expertise to perform the work proposed on a scale of 0 to 5 (5 indicated the highest level of expertise). This process is explained more fully in appendix III.

Table 3.1: Relevant Expertise of Principal Investigators as Related to Outcome of Grant and Contract Applications (Fiscal Year 1986)

Outcome of application	Total applications	Rating code 0-3	Rating code 4-5
Grants			
Funded	39	13	26
Approved but not funded, PS of 225 or less	21	12	9
Approved but not funded, PS of 226 or more	56	34	22
Disapproved	36	27	9
Totals	**152**	**86**	**66**
Contracts			
Funded	51	19	32
Approved but not funded, in CR	15	8	7
Approved but not funded, not in CR	39[a]	23	16
Unacceptable	22	15	7
Totals	**127[a]**	**65**	**62**

PS = grant priority score

CR = contract competitive range

[a]One application was received and processed without a curriculum vitae for the principal investigator; therefore an independent assessment of experience was not possible.

Of the 86 grant applicants with ratings of 0 to 3, 13 (15 percent) were funded; for the 66 with scores of 4 or 5, 26 (39 percent) were funded. Of the 65 contract applicants with scores of 0-3, 19 (29 percent) were funded; for the 62 with scores of 4 or 5, 32 (52 percent) were funded.

For both grants and contracts, the chances of being funded generally increased with each incremental increase in the applicants' scores. That

[1]For each of our analytical tables, we have separated the results of the NIH funding decisions into four categories. For grants these are: funded; approved but unfunded with a priority score of 225 or less; approved but unfunded with a priority score of 226 or more; and disapproved. For contracts, the categories are: funded; unfunded but approved and in the competitive range; unfunded but approved and not in the competitive range; and unacceptable. For further information, see appendix III.

is, a higher percentage of applicants with scores of 5 were funded than those with a score of 4.

NIH has not compiled data on the effect of an applicant's relevant expertise on success in being funded.

Lack of relevant experience of the principal investigator was mentioned by reviewers on 30 percent of the 92 grant applications that were disapproved or had priority scores of 226 or more. It also was mentioned on 52 percent of the 62 contract applications that were unacceptable or were not funded and not in the competitive range.

Age of Principal Investigators

Younger principal investigators (age 40 and under) who applied for NIH AIDS grants and contracts in fiscal year 1986 had better success in being funded than older investigators (see table 3.2). The amounts of individual awards were, however, higher on average for the older investigators. Our analysis is consistent with data compiled by NIH for all traditional research project grants awarded in fiscal year 1985.

Table 3.2: Age of Principal Investigators as Related to Outcome of Grant and Contract Applications (Fiscal Year 1986)

	Grants				Contracts[a]			
	Age 40 and under		Age 41 and over		Age 40 and under		Age 41 and over	
Outcome of application	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
Funded	18	30	21	23	17	47	34	38
Approved but not funded: PS of 225 or less or in CR	7	12	14	15	2	6	13	15
Approved but not funded: PS of 226 or more or not in CR	21	35	35	38	11	30	28	31
Disapproved or unacceptable	14	23	22	24	6	17	15	17
Totals	**60**	**100**	**92**	**100**	**36**	**100**	**90**	**100**

PS = grant priority score

CR = contract competitive range

[a]Age was unavailable for two contract applicants.

Younger grant applicants submitted 35 percent fewer applications (60 versus 92) than older applicants but had a 7 percent higher funding rate (30 versus 23 percent). Of 60 applicants who were 40 or under, 18 (30 percent) were funded, while of the 92 who were 41 or over, 21 (23 percent) were funded. The disapproval rate for grant funding was about the same for both age categories.

For contracts, younger applicants submitted 60 percent fewer applications (36 versus 90) than those 41 or older but had a 9-percent higher funding rate. Of the 36 younger applicants, 17 (47 percent) were funded, while 34 (38 percent) of the 90 applicants 41 or over were funded. The percentage of contract applications found unacceptable was the same for both age categories.

Older funded applicants received grant awards[2] about $23,000 higher and contract awards[2] over $102,000 higher, on average, than younger funded applicants. Funded grant applicants were slightly younger on average (43) than those approved but unfunded (44) or disapproved (44). For contracts, the average age was the same (45) for applicants who were funded and who were acceptable but not in the competitive range. The average age for applicants with unacceptable applications was 46 while it was 49 for applicants who were acceptable and in the competitive range. Ages of all applicants ranged from 28 to 66 for grants and 26 to 68 for contracts.

The above results are consistent with the most recent (1985) data for all NIH traditional research project grants published by NIH's Division of Research Grants (DRG). These data, based on an analysis of about 17,000 applications, showed applicants aged 26-40 to have better priority scores and higher funding rates than all age groups 41-70. NIH did not develop similar information for contracts.

Sex of Principal Investigators

Male and female applicants for NIH AIDS grants in fiscal year 1986 were funded at the same rate. Males, however, submitted about five times as many applications as females. While 26 percent of males' grant applications were disapproved, 15 percent of females' applications were disapproved (see table 3.3).

For contracts, 41 percent of male applicants received funding compared with 30 percent of female applicants. But there were only 10 contract applications from female principal investigators. No females' applications for contracts were found unacceptable but 19 percent of males' applications were.

Data published by DRG shows that, NIH-wide, men had better grant priority scores on average than women and better success rates. For example,

[2]These computations are based on fiscal year 1986 costs only.

Table 3.3: Sex of Principal Investigators as Related to Outcome of Grant and Contract Applications (Fiscal Year 1986)

	Grants				Contracts			
	Male		Female		Male		Female	
Outcome of application	No.	%	No.	%	No.	%	No.	%
Funded	32	26	7	26	48	41	3	30
Approved but not funded: PS of 225 or less or in CR	16	12	5	18	12	10	3	30
Approved but not funded: PS of 226 or more or not in CR	45	36	11	41	36	30	4	40
Disapproved or unacceptable	32	26	4	15	22	19	0	0
Totals	**125**	**100**	**27**	**100**	**118**	**100**	**10**	**100**

PS = grant priority score

CR = contract competitive range

in 1985, 31.1 percent of men with medical degrees and 33.1 percent of men with PhDs were funded, while 25.1 percent and 29.7 percent, respectively, of women with similar degrees were funded. Similar data was not compiled for contracts.

Prior Service on NIH-Chartered Review Committee

NIH funded applicants who had previously served on an NIH-chartered review committee at a higher rate than those who had not served on such committees. NIH keeps permanent records of persons who have served on chartered review committees but not on those who have served on ad hoc, unchartered committees. Eighteen of the 152 grant applicants and 9 of the 128 contract applicants had served on a chartered review committee, we found (see table 3.4).

Table 3.4: Service on an NIH Review Committee as Related to Outcome of Grant and Contract Applications (Fiscal Year 1986)

	Grants					Contracts				
		Yes		No			Yes		No	
Outcome of application	Total	No.	%	No.	%	Total	No.	%	No.	%
Funded	39	6	33	33	25	51	4	44	47	40
Approved but not funded: PS of 225 or less or in CR	21	2	11	19	14	15	4	44	11	9
Approved but not funded: PS of 226 or more or not in CR	56	9	50	47	35	40	1	12	39	33
Disapproved or unacceptable	36	1	6	35	26	22	0	0	22	18
Totals	**152**	**18**	**100**	**134**	**100**	**128**	**9**	**100**	**119**	**100**

PS = grant priority score

CR = contract competitive range

Of the 18 grant applicants who had served on a review committee, NIH funded 6 (33 percent) and of the 134 who did not, NIH funded 33 (25 percent). Of the nine contract applicants who had served on a review committee, NIH funded four (44 percent), while of the 119 who had not, NIH funded 47 (40 percent).

NIH has not compiled information on the effect of service on a chartered review committee on an applicant's success in getting funded. But NIH officials pointed out that prior success in getting NIH funding was a factor in appointing members to a chartered review committee. Also, NIH considered these researchers to be the "cream of the crop."

Prior Recipients of NIH Grants or Contracts

Applicants who had been prior recipients of NIH grants or contracts did better than those without prior awards.

Table 3.5: Analysis of Grant Applications Based on Number of Prior Grants Received (Fiscal Year 1986)

Outcome of application	Total applications	No. of grants previously received			
		None	1 or 2	3 or 4	5 or more
Funded	39	16	12	7	4
Approved but not funded: PS of 225 or less	21	11	5	4	1
Approved but not funded: PS of 226 or more	56	26	14	12	4
Disapproved	36	21	7	7	1
Totals	**152**	**74**	**38**	**30**	**10**

PS = grant priority score

Table 3.6: Analysis of Contract Applications Based on Number of Prior Contracts Received (Fiscal Year 1986)

Outcome of application	Total applications	No. of grants previously received			
		None	1 or 2	3 or 4	5 or more
Funded	51	31	9	9	2
Approved but not funded, in CR	15	7	7	1	0
Approved but not funded, not in CR	40	31	8	0	1
Unacceptable	22	16	3	2	1
Totals	**128**	**85**	**27**	**12**	**4**

CR = contract competitive range

For grants, 16 (22 percent) of 74 applicants with no prior awards were funded. Twelve (32 percent) of 38 applicants with 1 or 2 prior awards were funded, 7 (23 percent) of 30 applicants with 3 or 4 prior grants were funded, and 4 (40 percent) of 10 applicants with 5 or more prior awards were funded. Thus, 22 percent of applicants with no prior awards were funded, and 29 percent of those with prior awards were funded.

For contracts, 31 (36 percent) of 85 applicants with no prior awards were funded. Nine (33 percent) of 27 applicants with 1 or 2 prior awards were funded, 9 (75 percent) of 12 applicants with 3 or 4 prior awards were funded, and 2 (50 percent) of 4 applicants with 5 or more prior awards were funded. Thus, 36 percent of applicants with no prior awards were funded, and 47 percent of those with prior awards were funded.

NIH has not compiled information on the effect of previous grants or contracts from NIH on applicants' success in being funded.

Investigators Associated With Top 20 Organizations Receiving Funding

For fiscal year 1986, there was no difference in funding rates for grant applicants who were associated at the time of the application with the 20 organizations that had received the most NIH funds in the previous year and those with no such association. However, contract applicants associated with a top-20 organization were funded at a significantly higher rate than applicants who were not (see table 3.7). This analysis is based on NIH's listing of the amounts awarded to organizations in fiscal year 1985.

Table 3.7: Association of Principal Investigators With Top 20 NIH-Funded Organizations as Related to Outcome of Grant and Contract Applications (Fiscal Year 1986)

	Grants					Contracts				
		Associated		Not associated			Associated		Not associated	
Outcome of application	Total	No.	%	No.	%	Total	No.	%	No.	%
Funded	39	7	26	32	26	51	15	62	36	35
Approved but not funded: PS of 225 or less or in CR	21	7	26	14	11	15	4	17	11	10
Approved but not funded: PS of 226 or more or not in CR	56	9	33	47	38	40	4	17	36	35
Disapproved or unacceptable	36	4	15	32	25	22	1	4	21	20
Totals	**152**	**27**	**100**	**125**	**100**	**128**	**24**	**100**	**104**	**100**

PS = grant priority score

CR = contract competitive range

For grants, 7 (26 percent) of 27 applicants associated with a top-20 organization in receipt of NIH funds were funded and 32 (26 percent) of 125 of those not so associated were funded. For contracts, 15 (62 percent) of 24 applicants associated with a top-20 organization were funded and 36 (35 percent) of 104 without such not association were funded.

According to NIH's Division of Research Grants, traditional research project grant applications submitted by the 20 top-ranked organizations in fiscal year 1985 NIH-wide fared better than applications submitted by other organizations. For example, 31 percent of new applications from top-20 organizations had priority scores of 100-175 (the best scores) compared with an average of 26 percent for all new applications. NIH did not compile data on the percent of applications that were funded in these two groups.

We also analyzed the outcome of the applications according to whether principal investigators were associated with organizations that were in the top 20 in receiving NIH funds for AIDS research in fiscal year 1986. Such investigators, we found, were more likely to be funded than those that were not, especially for contract applicants. For the 152 grant applicants, 9 (32 percent) of 28 applicants associated with an organization in the top 20 were funded compared with 30 (24 percent) of the 124 not from those organizations. For the 128 contract applicants, 22 (71 percent) of 31 applicants associated with the top-20 organizations were funded compared with 29 (30 percent) of the 97 not from these organizations.

The results of this latter analysis, however, can be misleading. The awarding of the grant or contract could move the organization with which the principal investigator was associated into the "top 20" category for AIDS funds. Thus, it could be a self-fulfilling situation. In fiscal year 1986, the awarding of about 10 average grants or 1 large contract to an organization would have placed it in the top 20. NIH did not compile information to determine which organizations were in the top 20 in receiving AIDS funds prior to fiscal year 1986.

NIH officials expressed the view that the success of the top 20 organizations might be reflective of large organizations or geographic areas that had the patient population needed to carry out some of the research.

Degree Held by Principal Investigators

Most applicants for AIDS grants or contracts included in our review had a Doctor of Philosophy (PhD) or Doctor of Medicine (MD) degree. The PhD degrees were in such fields as microbiology, biochemistry, and physiology. Of these two categories, PhDs had the higher funding rate for grants but also the higher application disapproval rate. For contracts, MDs had the higher funding rate and about the same unacceptable application rate as PhDs (see table 3.8).

Table 3.8: Degree Held by Principal Investigators as Related to Outcome of Grant and Contract Applications (Fiscal Year 1986)

	Degrees held				
	Total	**PhD**	**MD**	**PhD/ MD**	**Other**
Grants					
Funded	39	20	12	4	3
Approved but not funded: PS of 225 or less	21	9	9	0	3
Approved but not funded: PS of 226 or more	56	22	25	7	2
Disapproved	36	25	10	1	0
Totals	**152**	**76**	**56**	**12**	**8**
Contracts					
Funded	51	26	19	0	6
Approved but not funded, in CR	15	9	4	1	1
Approved but not funded, not in CR	40	28	10	1	1
Unacceptable	22	12	6	0	4

PS = grant priority score

CR = contract competitive range

Of 76 grant applicants with PhD degrees, 20 (26 percent) were funded and 12 (21 percent) of 56 with medical degrees were funded. Thirty-three percent of the applications from PhDs were disapproved, while 18 percent of the applications from MDs were disapproved. This analysis excludes applicants who had more than one degree. For contracts, 26 (35 percent) of 75 applicants with PhDs were funded and 19 (49 percent) of the 39 applicants with MDs were funded.

NIH officials were of the opinion that the differences between MDs and PhDs reflected the skills necessary to carry out particular research efforts. For example, in 1986, more money was put aside to fund contracts for AIDS Treatment Evaluation Units, which generally are awarded to MDs.

According to NIH-wide data on traditional research project grants compiled by the Division of Research Grants, applications from PhDs had slightly better scores than applications from MDs. PhDs also had a smaller percentage of disapproved applications and a higher percentage of applications with scores of 100-175 (the best scores).

NIH Grant Review and Award Process

Applications for NIH grants are either solicited or unsolicited. Unsolicited applications, usually termed investigator-initiated, are submitted by a principal investigator on his or her initiative. Solicited applications are submitted in response to a request for application, issued by an institute to expedite development of a program or stimulate research in a specific scientific area. An RFA is an invitation to the research community to submit applications for a one-time competition for specified research grant funds.

Review and Approval Process for Unsolicited Applications

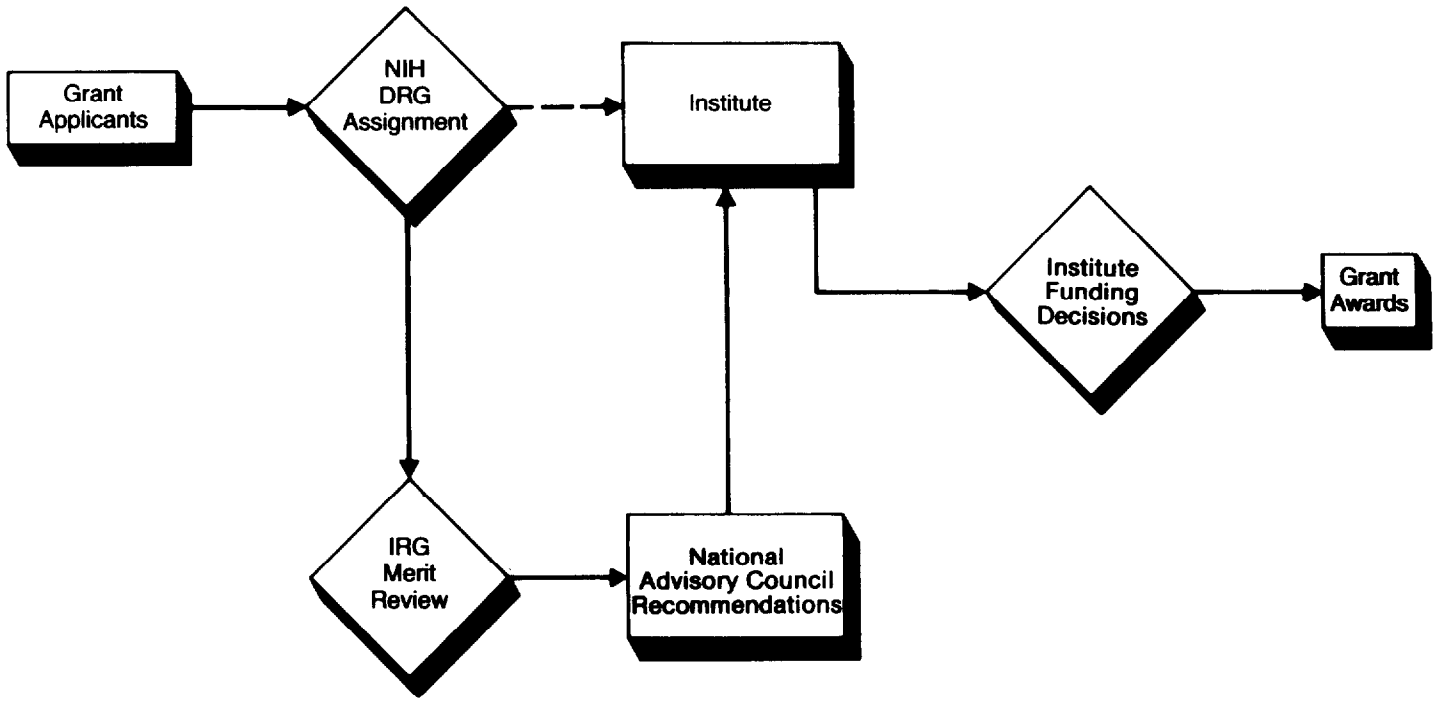
Dual Review Process Used

For grant applications, NIH uses an external "dual review system." This consists of an initial review for scientific merit by scientists actively engaged in research and a second review by a statutorily mandated national advisory council or board comprising scientific, medical, and public representatives. Unsolicited applications for grants are submitted to NIH's Division of Research Grants to coincide with a specified receipt date related to one of three yearly grant application review and funding cycles (see fig I.1). DRG assigns the applications to both an external initial review group and a specific institute according to detailed assignment guidelines and the institute's mission as well as its program interests and mandates.

IRGs are established for a particular field of science and operate under the administrative management of the DRG. Generally, the members of the IRGs are not federal employees but are actively involved in research of the type they will be evaluating. The members review and discuss the applications and by majority vote recommend approval, disapproval, or deferral. A recommendation for deferral occurs when the IRG considers the available information inadequate to permit a recommendation for approval or disapproval. Each application recommended for approval is assigned a priority score based on scientific merit. The scores range from 100 to 500, with 100 being the best score and 500 the least acceptable.

Each IRG meeting is monitored and facilitated by an NIH executive secretary who is a science administrator in the employ of DRG. The executive

Figure I.1: NIH Review Process for Unsolicited Grant Applications



secretary is responsible for writing a summary of the review and discussion for each application. A copy of the summary statement (the "pink sheet") is sent to the applicant and to the appropriate institute.

At the second level of the NIH dual review system, each institute's national advisory council or board generally reviews the summary statements prepared at the IRG meeting rather than the applications themselves. All applications, except those for which direct costs are less than $50,000, must be recommended for approval by the national council or board before they can be funded. The council or board's recommendation on the proposed project is based on its scientific merit and relevance to the institute's programs and priorities.

The council or board generally votes "en bloc concurrence" (i.e., as a group) with the IRG's recommendations as presented in the summary statements, although some applications are discussed individually. It is rare that the council does not concur with the IRG's recommendation,

according to an NIH official. However, if such agreement is absent, the council may revise the recommendation, although it cannot change the IRG's priority score. The council or board also can require that the IRG rereview an application.

NIH's external peer review process ends with the national advisory council or board review. The institute director then may fund any grant application for which the IRG and the advisory council or board have recommended approval. Generally, applications are funded according to the priority score assigned until all available grant funds are obligated, although there may be exceptions as discussed below. Funding decisions for grants are the prerogative of the awarding institutes and are not appealable.

Funding Procedures Varied Among Institutes Reviewed

In accordance with the flexibility built into the NIH grant review and funding process, each of the three institutes we reviewed varied in its funding procedures. After listing its approved applications in priority score order from best to least acceptable (from 100 to 500), each institute establishes a "payline"—a priority cut-off score below which a grant cannot be funded without additional institute approvals. The cut-off score is based on such items as the anticipated budget, the projected number of applications to be received, and historical data. (For example, in fiscal year 1986 NIAID's payline was 145.) The variations among the institutes are as follows:

- NCI, through its executive committee, establishes its payline for each of the three review cycles each year, according to NCI's Acting Deputy Director and the Director of its Division of Extramural Activities. After each cycle, NCI reassesses where the payline should be set and may change it for the next cycle. NCI policy generally is to award grants in straight priority scoring order. However, it may skip (not fund) an application above the payline or fund an application below the payline. All such exceptions must be accompanied by a written justification approved by the NCI executive committee. Members of the committee include the Director, Deputy Director, Associate Director, Associate Director for Administrative Management, the five division directors, and the Director of Staff Operations, who serves as its executive secretary. At the end of the fiscal year, each division director is required to present a summary of approved exceptions to the National Cancer Advisory Board.
- NHLBI uses a "percentiling" system in making its funding decisions. (This process was adopted NIH-wide beginning with the February/March 1988

review cycle for applications to be considered at the October 1988 advisory council meetings). "Percentiling" refers to the ranking of approved grant applications along a 100-percentile band. The percentile assigned to an application depends on where its priority score falls compared with all other applications approved by that review group in the current cycle and the previous two cycles in which the review group participated. Among review groups, average priority scores and distributions vary, and some groups may be tougher scorers than others. This system provides a common denominator that helps in comparing applications reviewed by different groups. Thus, an application in the 90th percentile of one review group would be considered comparable to an application in the 90th percentile of another review group, regardless of the assigned priority scores.

NHLBI lists approved applications in order of their assigned percentiles and makes most awards on the basis of this listing until all available funds are obligated. However, the institute may decide to skip some applications so it can fund others with a higher overall programmatic priority. Final funding decisions are made by the Director and the staff of the institute.

- NIAID establishes a single payline for all three review cycles at the start of each fiscal year, according to the Director of NIAID's Extramural Activities Program and the Chief of NIAID's Grants Management Branch. Using the priority score, NIAID funds all applications above that payline. This payline may be lowered near the end of a fiscal year if sufficient funds are available.

  During the year, NIAID also may fund applications below the payline on a selective basis, as follows. A program office makes recommendations, supported by a written justification, of applications with priority scores below the payline it believes should be funded. These recommendations are submitted to a special committee made up of the NIAID Director, Deputy Director, Director of the Extramural Activities Program, the Program Director, the Executive Officer, and the Budget Officer. The Program Director presents his/her reasons to the committee for the grants selected and the recommended funding order.

  At the conclusion of this committee's meeting, a list of grants approved by the committee is compiled and submitted to the advisory council for its review and concurrence. The council may adjust the funding order of these grants. After the council meeting, NIAID may decide to fund a portion of these applications. Any applications on this list that remain

unfunded are carried forward until the end of the fiscal year when final funding decisions are made.

Review and Approval Process for Solicited Applications

NIH's review of solicited applications for grant funding is similar to the process for unsolicited applications. Generally, the Division of Research Grants does not need to decide to which institute a solicited application should be assigned. Usually, it is referred automatically to the institute that issues the Request for Application. DRG referral staff do, however, review responses to RFAs to ensure appropriate assignments.

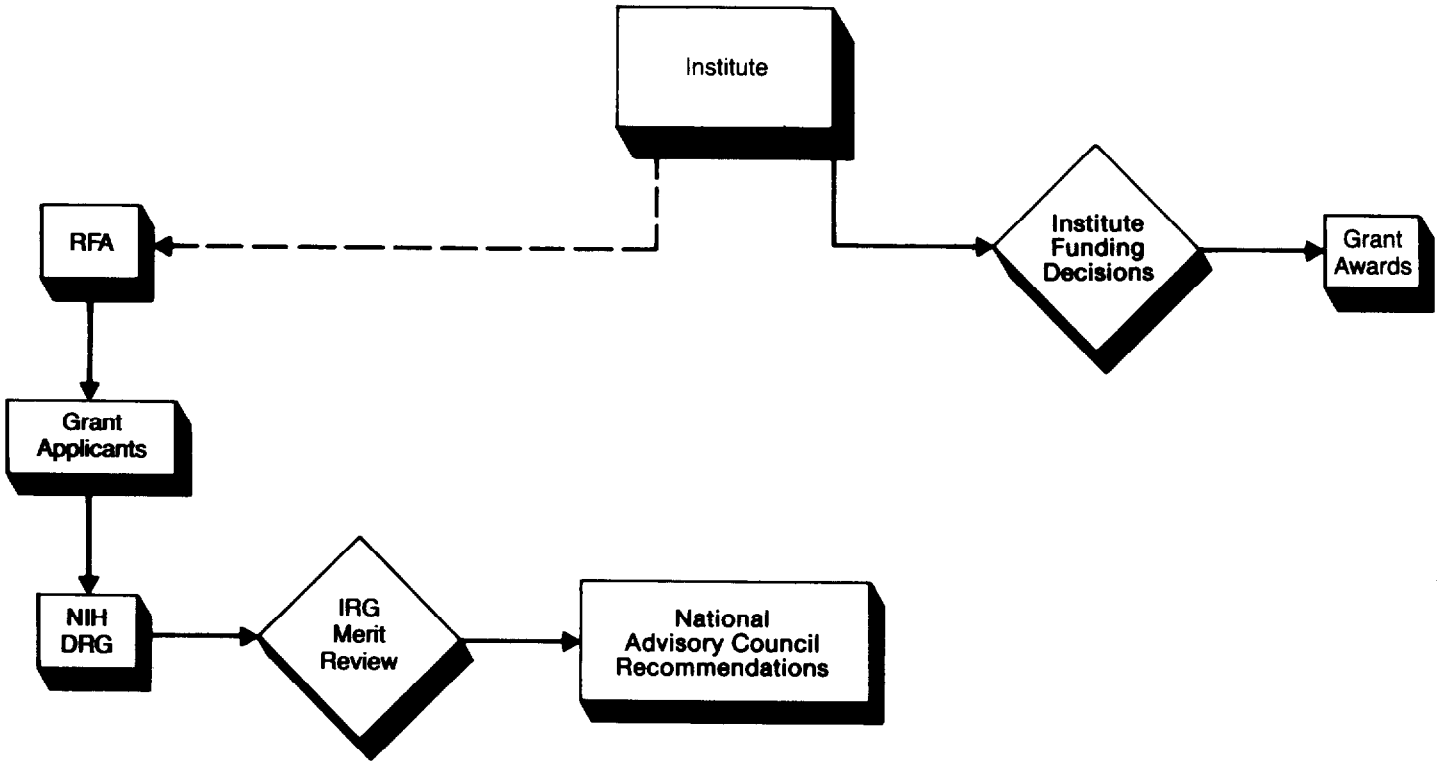
The review and approval process, as illustrated in figure I.2, is then as follows:

- An IRG established by and under the administrative management of the individual institute's Division of Extramural Activities conducts the initial review. This may be a chartered institute IRG or a special ad hoc IRG set up for a specific review. The general procedures of the institute IRGs parallel those for IRGs in the Division of Research Grants.
- Following its review of the application, the IRG recommends approval, disapproval, or deferral and assigns priority scores to the approved applications.
- The IRG executive secretary is responsible for writing a summary statement for each application reviewed and sends a copy to the principal investigators named in the applications.
- The institute's advisory council or board reviews and concurs with or revises the IRG's suggested actions.

The institute's decision on which grants to fund occurs after council or board approval.

Because funds are reserved for solicited applications, this decision can result in funding a solicited application with a higher (poorer) score than an unsolicited application that was not funded. However, the institute has the authority to not fund any of the applications if it believes none are worthy of support.

Figure I.2: NIH Review Process for Solicited Grant Applications



NIH Contract Review and Award Process

A contract is used when an institute wants to arrange for the investigation or performance of a directed scientific project with a well-defined statement of work. The awarding institute establishes the plans, parameters, and detailed requirements for contract-supported projects. To initiate a contract, the institute first obtains a scientific peer review of the concept, refines the plans based on the concept review, and then issues a request for proposal. Generally, proposals are due 60 days from the date the RFP is issued; 45 days is the minimum amount of time allowed by statute.

Internal Review Process Utilized

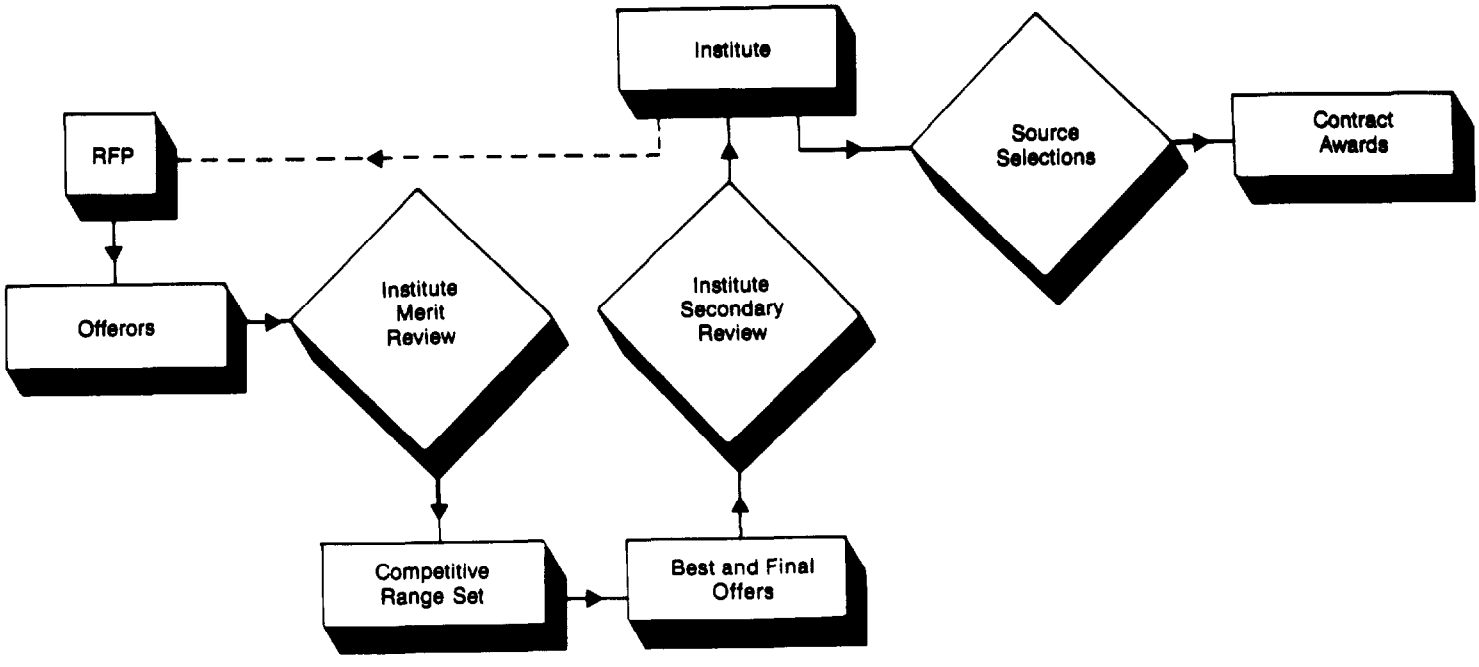
After proposals are received, they undergo a scientific merit review and technical evaluation. A second or final review of revised proposals is performed by senior scientific and contracting staff of the institutes and other experts. Approval by an institute's national advisory council or board is not required. The review process is illustrated in figure II.1.

Peer review groups, established and administratively managed by each institute's Division of Extramural Activities, first review the proposals. The group may be a standing chartered review committee or an ad hoc review group. An institute sets up an ad hoc review group when the volume of proposals received is beyond the capacity of the chartered committees or where the science called for in the RFP is so unique that a peer review group with special expertise is needed.

The scientific review differs from that of grant applications in that contract proposal reviewers are bound by the evaluation criteria identified in the RFP. The RFP not only defines the evaluation criteria but assigns a weight to each criterion. For example, the adequacy and feasibility of the proposed approach might be given a weight of 30 percent of the total score. The peer review group meets and discusses each proposal separately, recommends it as either acceptable or unacceptable, and gives it a numeric score, based on the specific evaluation criteria.

At the conclusion of the meeting, the executive secretary of the group, who oversees the meeting, is responsible for writing a summary report that becomes a permanent record in the contract file. For each proposal, the summary includes the peer review group's recommendation of acceptable or unacceptable, the numerical score, an evaluation of the proposal's strengths and weaknesses, any reservations or qualifications raised during the review, and any questions that should be raised in further discussions or negotiations with the offerer. Concurrent with this

Figure II.1: NIH Review Process for Contract Proposals



review, the contracting officer performs an initial business evaluation of each proposal.

The contracting officer determines, as set forth in the Federal Acquisition Regulations, which proposals are in the competitive range. A proposal must be included in the competitive range, according to Department of Health and Human Services' Acquisition Regulations, unless there is no possibility it can be improved sufficiently to receive an award. Guided by the review group's scores and recommendations, the contracting officer generally looks for a natural break in the scoring to select the proposals to include in the competitive range. After this is determined, the applicants are notified of the review results.

Applicants in the competitive range begin negotiations with the institute by answering a series of questions developed by the peer reviewers, project officer, and contracting officer on both technical and business issues. The contracting officer then asks each applicant to submit a best and final offer. All questions not resolved in writing during previous discussions are addressed in the final offers.

Best and final offers are subject to final review by the contracting officer and project officer with assistance from others as necessary. The first review group may assist in this effort or a second review group, independent of the first review group, may be established to assist in the review. At this time, the proposals may be rescored in those evaluation areas where there is new information. This second evaluation produces a ranking that aids the contracting officer in selecting the contractors. Selections are forwarded to the institute's management for concurrence.

Procedures Vary Among Institutes Reviewed

NIH allows some variations between its procedures and those of the institutes, as described below. Generally, these variations concern the membership of the institutes' secondary review groups and the point in the overall review process that the groups become involved.

- NCI establishes a secondary review group, referred to by NCI as a source evaluation group, to review the peer review group's scoring and recommend a competitive range to the contracting officer. The members of the secondary review group are federal employees having appropriate expertise in the project area. Peer review group members do not participate in the secondary review group activity. The latter group, however, uses the peer group's summary report as its basis for recommending a competitive range. Also, the peer group's executive secretary usually attends the evaluation group's meeting to answer questions about the technical evaluation.

  After best and final offers are submitted, the secondary review group reconvenes to review and sometimes rescore the offers. It then makes recommendations to the contracting officer, who makes the selections.

- NHLBI uses a similar group, the secondary review group, to review the recommendations and evaluations of the peer review group before the contracting officer establishes the competitive range. The group includes NHLBI program staff and the contracting officer. Experts from other institutes, other federal agencies, or outside the federal government may be invited to assist in the secondary review. NHLBI officials told us they consider the peer review group as a tool to advise the contracting officer and program staff. The secondary review group may disagree with the peer review group's scores and assign new scores. If proposals are rescored, clear and detailed reasons must be documented. At the time of

our review, this rescoring was approved by section heads within the NHLBI Contracts Operations Branch.

Secondary review allows for inclusion within the competitive range of a proposal that would not otherwise have been included. Likewise, it may serve to eliminate a proposal that would have been included had the range been established using only the scores assigned by the peer reviewers. Following our review at NHLBI, officials changed the review procedures to require approval of the rescoring by the Chief of the Contracts Operations Branch.

Following determination by the contracting officer of the competitive range, NHLBI conducts written and oral discussions with all competitive offerers. They are advised of any deficiencies in their proposals, an attempt is made to resolve technical deficiencies, and contractual terms and conditions are discussed. Also, the offerers are given an opportunity to support, clarify, and improve both their technical and cost proposals.

The secondary review group participates again, reviewing best and final offers submitted after negotiations are completed. NHLBI's project officer summarizes the secondary review recommendations regarding contractor selections for the contracting officer's concurrence. According to an NHLBI official, these recommendations ultimately are reviewed and approved by the Chief of the Contracts Operations Branch and the director of the division initiating the program.

- In NIAID, the Chief of the Contract Management Branch, in conjunction with the contracting officer, determines the competitive range. This is done after considering the peer review group's ranking and program staff recommendations. After best and final offers are received, a secondary review group is established. The members include one or two from the peer review group, the project officer, and the Director or Deputy Director of the Extramural Activities Program. This group reviews the offers and can rescore them so long as it justifies and documents its changes. It makes recommendations to the contracting officer who makes the selection decisions. Final approval of selections is made by the Deputy Director and Executive Officer of NIAID.

Methodology for Determining Characteristics of Principal Investigators

To compare the characteristics of the principal investigators who applied for fiscal year 1986 AIDS grants and contracts from NIH, we grouped the applications into four categories. Because there was a wide range of priority scores that could be assigned to a grant application, from 100 to 500 (100 being the best), we wanted to distinguish between applications that had a realistic chance of being funded, judging from their assigned priority scores, and those that were unlikely to be funded. We established a priority score of 225 as the dividing line. Given historical data, it was highly unlikely that an application for a traditional research project or First Independent Research Support and Transition award with a priority score of higher than 225 would be funded. In fact, of the applications in our universe, only two with a score above 186 were funded.

Based on this distinction, we categorized all grant applications reviewed as either: (1) funded; (2) approved but unfunded, with a priority score of 225 or less; (3) approved but unfunded, with a priority score of 226 or more; or (4) disapproved.

Similarly, we categorized all contract proposals reviewed as either: (1) funded; (2) unfunded but approved and in the competitive range; (3) unfunded but approved and not in the competitive range; or (4) unacceptable. Proposals that were acceptable but not in the competitive range were shown separately because, although there was no possibility that they would be funded, they were rated as acceptable and thus were distinguishable from the unacceptable proposals.

To compile the characteristics of each of the 280 principal investigators who applied for an AIDS grant or contract in fiscal year 1986, we completed an individual data collection instrument for each application in our universe, regardless of whether the application was funded.

To determine the relevant expertise of principal investigators to do the research work proposed, we sought the independent opinions of three officials from NIH's Office of Extramural Programs. We asked them to examine the statement of work from the request for proposal (for contracts) or the abstract from the grant application, as well as the principal investigator's curriculum vitae or biographical sketch. Working from this information, they rated each principal investigator's relevant expertise on a scale from 0 to 5. A rating of 0 indicates no relevant expertise and 5 indicates the relevant expertise was outstanding. The NIH officials had not been involved in the review of these grant applications and contract proposals in 1986 nor were they informed during this exercise as

to whether the applications they reviewed had been funded. The three officials have science backgrounds, one having a PhD in biochemistry, another in microbiology, and the third in physiology.

We established 40 as an appropriate "age cutoff" to distinguish between a young researcher and an older researcher, basing this on discussions with and the recommendation of the Deputy Director for Extramural Research and Training, NIH. This age allows sufficient time to obtain advanced degrees and minimal experience needed to do research.

To establish the principal investigator's previous experience in applying for, and being awarded, grants or contracts prior to 1986, we reviewed files provided by the Division of Research Grants for each principal investigator in our universe. Because NIH does not keep data on contract proposals that were submitted but not funded, we were able to collect data only on funded contract proposals. We used the same files to ascertain if the principal investigator had been a member of an NIH chartered review group.

Because 40 of the 128 contract proposals were for research support services and not direct research, we recomputed the data for each principal investigator characteristic after excluding these 40 proposals. This recomputation did not change the results for any of the characteristics discussed in chapter 3.

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