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REPORT TO THE CONGRESS

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

Better Controls Needed Over Biomedical Research Supported By The National Institutes Of Health

Department of Health, Education, and Welfare

The National Institutes of Health could improve the way it funds research projects to better insure that those with the greatest scientific merit are funded. Many researchers have not complied with the terms of previous grant awards, and the Institutes is currently supporting some of these researchers. Also, a formal system is needed for initiating intramural research projects conducted by National Institutes of Health scientists.

HRD-76-58 ~~707473~~ JULY 22, 1976

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-164031(2)

To the President of the Senate and the
Speaker of the House of Representatives

This report describes certain changes that could be made by the National Institutes of Health of the Department of Health, Education, and Welfare to improve the quality of the biomedical research projects it supports. We made our review because of the large amount of money being spent for biomedical research.

We made our review pursuant to the Budget and Accounting Act, 1921 (31 U.S.C. 53) and the Accounting and Auditing Act of 1950 (31 U.S.C. 67).

We are sending copies of this report to the Director, Office of Management and Budget and the Secretary of Health, Education, and Welfare.

Comptroller General
of the United States

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ABBREVIATIONS

GAO	General Accounting Office
HEW	Department of Health, Education, and Welfare
NIAID	National Institute of Allergy and Infectious Diseases
NICHD	National Institute of Child Health and Human Development
NIEHS	National Institute of Environmental Health Sciences
NIH	National Institutes of Health

COMPTROLLER GENERAL'S REPORT TO THE CONGRESS

BETTER CONTROLS NEEDED OVER BIOMEDICAL RESEARCH SUPPORTED BY THE NATIONAL INSTITUTES OF HEALTH Department of Health, Education, and Welfare

D I G E S T

The National Institutes of Health, an agency of the Department of Health, Education, and Welfare, is composed of 11 institutes and supports the majority of biomedical research done in the United States. In fiscal year 1974 it obligated about $2 billion for this purpose. (See p. 1.)

GAO believes this report will especially interest the Senate Committee on Appropriations. The Committee stated in its report on the Department's fiscal year 1976 appropriation request that most of each year's funds are committed to ongoing projects, leaving little money to support new projects.

The Committee urged the Institutes to consider whether a different balance between old and new projects was desirable and, if so, how it could be accomplished without unduly disrupting productive ongoing research.

Grantees do most of the research funded by the Institutes. Grantees compete for funding on the basis of their grant application's scientific merit, which is determined by authorities in selected scientific fields. Approved grantees generally receive funding for 3 years. After the approval period expires, applications for continued financial support are treated as new grant applications and grantees must again compete for funding.

At the three institutes GAO reviewed, nearly all noncompeting grants received funding for each year of the approved period, but funding was available for only 34 to 50 percent of competing grants. The Institutes should reassess noncompeting grants annually to insure that continued funding is desirable, because:

--Many unfunded competing grant applications had greater scientific merit, as evidenced by the priority scores assigned by scientific authorities, than some noncompeting grants which continued to be funded.

--About 44 percent of the noncompeting grants were not funded again after their approval period expired because, when competing with other grant applicants, their priority scores indicated they were of lower scientific merit.

The Institutes does not terminate a research grant when progress is poor and cannot, under existing regulations, terminate when

--significantly better applications, as evidenced by priority scores, could be funded or

--recent scientific developments or other events result in research being no longer of public benefit. (See p. 9.)

Even if program administrators identified ongoing research that they believed to be unnecessary or duplicative, these grants could not be terminated. Although the Institutes can withhold funds from a grantee, grant administrators differ on when this can be done. (See p. 10.)

The Institutes requires, as a condition of a grant award, that it receive certain reports from grantees at the end of a research grant period. These reports were not being submitted for many research grants. (See p. 21.) In addition, some grantees which had not met the reporting requirements under a previous grant were being funded by the Institutes under another grant. (See p. 23.)

In contrast to extensive peer review of research proposals in the Institutes' extramural research grant programs, the Institutes had no formal procedures for initiating new intramural research projects (those conducted by Institutes scientists in Institutes laboratories). (See p. 27.)

Individual projects normally received only the approval of the branch or laboratory chief where the research was to be done. Reviews of researchers' work by advisory groups within the Institutes concluded that some were doing work of questionable scientific merit or relevance to an institute's mission. They recommended terminating the work or taking other corrective action. (See p. 29.)

GAO is making a number of recommendations to the Secretary of the Department of Health, Education, and Welfare to help insure the Institutes support research proposals with the greatest scientific merit. The recommendations include

--developing a system to identify noncompeting grants with significantly less scientific merit than unfunded competing grant applications (see p. 19),

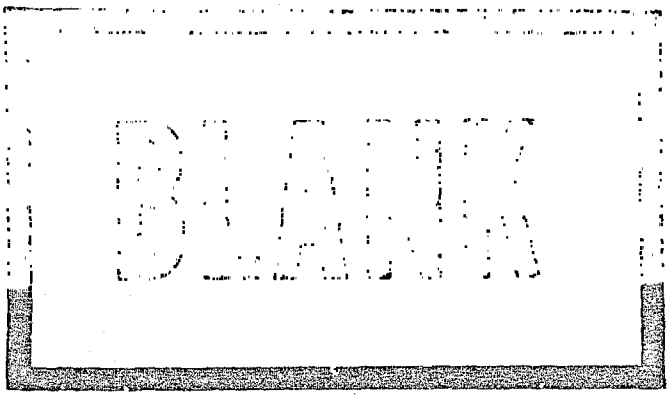
--changing the regulations to allow termination of research grants under certain conditions, such as when applications have significantly greater scientific merit, as evidenced by priority scores (see p. 19), and

--establishing a formal system for approving all intramural research projects. (See p. 32.)

The Department generally disagrees with these recommendations, stating they would be extremely costly with little prospect of appreciable benefits.

After evaluating the Department's comments, GAO continues to believe that implementing the recommendations would improve the research of the National Institutes of Health. The Department could implement the recommendations in a simpler and more effective manner than indicated in its comments, with a minimum of additional cost.

GAO is also making other recommendations to the Department for improving management practices with which it generally agreed.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CHAPTER 1

INTRODUCTION

Today, the National Institutes of Health (NIH), Department of Health, Education, and Welfare (HEW), is one of the world's foremost and prestigious biomedical research centers and is the focal point for Federal biomedical research and research support. The mission of NIH is to improve the health of the people of the United States. To achieve this it:

--Conducts biomedical research in its own laboratories.

--Provides grants to nonprofit organizations and institutions for research and for medical education, including improvements and construction of library facilities, buildings, equipment, and other resources.

--Provides grants for training research investigators.

--Awards research contracts to profit and nonprofit institutions.

--Supports biomedical communications through programs and activities of the National Library of Medicine.

NIH has 11 research institutes; each supports biomedical research programs. All but 1 institute are located on the NIH reservation in Bethesda, Maryland, where NIH also maintains hundreds of laboratories, a 516-bed clinical center (research hospital), and the National Library of Medicine. The National Institute of Environmental Health Sciences (NIEHS) is located at Research Triangle Park, North Carolina.

PROGRAM ACTIVITY

Research conducted by NIH scientists in NIH laboratories is referred to as the intramural program; research performed under NIH grants and contracts is referred to as the extramural program.

In fiscal year 1974 NIH obligated nearly $2 billion to support its research activities. Approximately $1 6 billion of this amount was used to support research programs, and the remainder was used for research training, construction, and overall management of NIH programs. In fiscal year 1975 NIH was appropriated $2.1 billion and paid about 38 percent of the cost of all health related research and development done in the United States.

The chart below shows NIH's total obligations in fiscal year 1974 and the obligations of the three institutes we reviewed: the National Institute of Child Health and Human Development (NICHD), the National Institute of Allergy and Infectious Diseases (NIAID), and NIEHS.

	NIH	NIAID	NICHD	NIEHS
	(millions)			
Research grants	$1,066	$71	$84	$16
Intramural research	134	21	14	8
Research and development contracts	335	12	21	2
Research training	210	11	17	5
Program management	97	4	7	1
Other programs and support	152	2	1	-
Total	$1,994	$121	$144	$32

During fiscal year 1974, about 70 percent of the research grants awarded by these three institutes were for traditional research grants, which are awards to institutions, in the name of a principal investigator, for discrete research projects. The balance of the grant funds was for other types of grants, such as program project grants, which support broadly based, long-term activities involving teams of scientists.

In fiscal year 1974 NIH received about 10,000 competing research grant applications. Of these applications, 74 percent were approved for funding, but funds were available for only 53 percent of the approved applications.

In recent years NIH has experienced a widening gap between the number of research grant applications approved and those it can fund. As a consequence of increased competition for research funds coupled with budget constraints, NIH must be able to identify and fund those projects, both extramural and intramural, having the greatest scientific merit and relevance to its mission

GRANTS FOR EXTRAMURAL RESEARCH

First stage

Scientists in the NIH Division of Research Grants read an application for a research grant and assign it to the institute responsible for supporting research in that scientific area. At the same time, they assign each application to 1 of approximately 50 study sections, or initial

review groups, which reviews the application for scientific merit. This review by a study section is the first stage of NIH's dual review process.

Most study sections have 12 to 16 members--authorities in their selected scientific fields. Each application is reviewed and discussed before receiving the study section's recommendation to approve, disapprove, or defer it.

The study section, as a whole, assigns a numerical priority score to each approved application on the basis of its scientific merit relative to the "state of the art" of a particular research area. A priority score of between 100 and 500, which represents an average of the individual scores given by study section members, is assigned to each application. The priority score indicates the relative scientific merit of the grant application, and the research institutes use it to rank a grant application for funding. The lower the priority score, the greater the scientific merit of the application. A study section can disapprove a grant application for a number of reasons, one of the most important being lack of scientific merit.

The Division of Research Grants adjusts the actual or "raw" scores assigned to approved grants by study sections. This adjustment (normalization) is made to account for scoring biases in each study section and is intended to place the scores of all study sections on the same scale so a given score will be comparable from one study section to another.

Second stage

Following the study section recommendations, all approved and disapproved grant applications are forwarded to the national advisory council of the appropriate institute. Each institute has a national advisory council, which must approve grant applications before they can be funded. These councils are the second stage of the dual review process and consist of approximately 12 to 18 members--leaders in fundamental and medical science, education, and public affairs.

While these advisory councils may review the scientific merit of a grant application, their primary responsibility is to evaluate whether applications relate to the mission and the needs of the respective institutes. They may either agree or disagree with the study section recommendations.

After the advisory council review, the institutes consider all approved applications for funding. Although the institutes may fund grant applications out of numerical order,

this is the exception rather than the rule. In addition, each institute receives the raw and the adjusted priority scores for each grant application.

Grant applications the institutes approve for funding are funded, on the average, for 3 years. During this 3-year period, a grantee does not have to compete for funds, and the grant is referred to as a noncompeting continuation research grant. If, at the end of an initially approved period, a grantee requests additional funding, it must again compete for available funds.

INTRAMURAL RESEARCH

NIH scientists conduct intramural research projects in NIH laboratories or the NIH clinical center. In contrast to extramural research grants, intramural research projects receive no peer review before they are begun.

Intramural projects at the institutes reviewed are directed by either the scientific director within each institute or the director of the institute who allots space and resources to individual research branches. Branch or section chiefs generally approve individual projects, subject to review by the scientific director.

In fiscal year 1974, NIH obligated $134 million for intramural research. Also in fiscal year 1974, NIAID, NICHD, and NIEHS obligated a combined total of $43 million for intramural research, 15 percent of their combined budgets of $297 million. This amount accounted for 32 percent of the total NIH obligations for intramural research.

NIH officials said intramural research:

--Allows administrative barriers between medical disciplines to be crossed, which cannot be done at medical schools.

--Permits a large number of medical skills to be brought together in one place, so quality biomedical research can be done.

--Is conducive to spontaneous, collaborative research efforts among scientists.

Intramural research also enables scientists to devote most of their time to their research, while under an extramural research grant a researcher's time is divided among research, teaching, and various administrative duties.

CHAPTER 2

NEED FOR BETTER APPROVAL PROCEDURES AND IMPROVED MONITORING OF GRANTS

The National Institutes of Health research institutes we reviewed funded noncompeting multiyear research grants during the period for which they were initially approved, without comparing their scientific merit with that of competing grant applications. However, many unfunded competing grant applications had greater scientific merit, evidenced by their priority scores, than some noncompeting grants that continued to be funded. About 44 percent of the noncompeting grants were not funded after their approval period expired, and they again had to compete for funds.

Continuing the funding of some noncompeting continuation grants may be desirable, even if their scientific merit may be less than unfunded competing applications. They should be reassessed before denying funds to new applications with significantly greater scientific merit. This cannot be done, partly because NIH does not have written guidelines delineating the type of review or specific tasks grant administrators must perform during their review of ongoing research.

If a grantee has complied with the terms and conditions of a grant award, NIH cannot terminate the grant for the convenience of the Government without the grantee's concurrence. Although NIH can withhold funds from a grantee for the remainder of an approved project period, it cannot rescind funds that were approved but unspent for the earlier part of the grant period. In addition, grant administrators differ on when funds should be withheld from a grantee.

NIH does not require the 11 institutes to use normalized priority scores in funding grants. Therefore, NIH has no assurance that applications with the greatest scientific merit are being funded. Some grants probably would not have been funded if normalized scores were used, and some would have been funded but were not.

UNFUNDED COMPETING APPLICATIONS WITH SCIENTIFIC MERIT GREATER THAN NONCOMPETING GRANTS

At the three NIH institutes reviewed, nearly all ($63.9 million worth) of the noncompeting multiyear traditional research grant applications were funded in fiscal year 1974. During the same period, these institutes were only able to fund between 34 and 52 percent of approved competing

traditional research grant applications for a total of $45.1 million. The chart below shows the funding of competing and noncompeting grants for the three institutes for fiscal year 1974.

Institutes	Noncompeting grants Amount	Noncompeting grants Number	Competing grants Amount	Competing grants Number	Percent of approved competing grants funded
	(millions)		(millions)		
National Institute of Environmental Health Sciences	$ 3.5	80	$ 2.4	37	34
National Institute of Child Health and Human Development	25.1	538	26.7	469	52
National Institute of Allergy and Infectious Diseases	35.3	704	16.0	327	46
Total	$63.9	1,322	$45.1	833	

A comparison of the normalized priority scores of approved, unfunded grant applications with the normalized priority scores of funded noncompeting multiyear grants for NICHD and NIAID showed that during fiscal year 1974, 287 unfunded research grant applications had priority scores equal to or better than the noncompeting grants that were funded.[1] An NIH official indicated that the normalization process generally permits priority scores to be compared validly from one year to the next.

In NIAID 144 competing grants were not funded, although they had equal or better priority scores than 20 noncompeting grants that were funded. In NICHD, 143 competing grants that were not funded had equal or better priority scores than 106 noncompeting grants that were funded.

Grant administrators are responsible for annually reviewing ongoing research grants for scientific progress, budgetary matters, and overall direction of research. The grant administrators we spoke with do not make critical reviews of noncompeting research grants to identify ongoing grants which might have less scientific merit or public benefit than competing grants that are approved but unfunded.

The need for NIH to continually assess the expected benefits of funding a noncompeting multiyear research grant is also evident from the number of grants that are not

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[1] NIEHS does not use normalized scores.

funded after the grant period expires. During fiscal year 1974, the three institutes did not fund 44 percent (223) of the multiyear traditional research grants whose terms had expired and for which renewal applications had been submitted. Of these grants, 180 were approved, but they did not have sufficient scientific merit to warrant support considering funding limitations of the respective institutes. NIH study sections disapproved the remaining 43 research grants.

The following table shows the number of competing renewal research grants that were approved and funded, approved and unfunded, and disapproved by each of the three institutes in fiscal year 1974.

	Approved-funded		Approved-unfunded		Disapproved		Total	
	No.	Percent	No.	Percent	No.	Percent	No.	Percent
NIEHS	15	42	16	44	5	14	36	100
NIAID	132	56	91	38	15	6	238	100
NICHD	133	58	73	32	23	10	229	100
Total	280	56	180	36	43	8	503	100

The reasons NIH study sections gave for disapproving the 43 grant applications shown above included (1) lack of detail in the grant proposal, (2) lack of research technique, (3) poor research design, and (4) poor progress under previous grant awards. For the 3 institutes, 14 grant applications were disapproved primarily on the basis of poor research progress in prior years. NIH had supported these 14 research grants for an average of 3 years. The individual grants had run as long as 6 years, and, in total, NIH awarded grant funds of at least $1.1 million to support these grants.

We reviewed the priority scores of the 16 approved and unfunded competing renewal applications for NIEHS, the 91 for NIAID, and the 73 for NICHD. NIEHS funded grants during fiscal year 1974 with priority scores of 212 or lower, and 10 of the 16 approved unfunded competing renewals had scores of 300 or more. NIAID funded grants with scores through 249, and 32 of the 91 approved unfunded competing renewals had scores of 300 or more. NICHD had 22 of its 73 applications with normalized priority scores of 300 or more.

LACK OF GUIDANCE FOR REVIEW OF ONGOING RESEARCH

After a research grant has been funded, the NIH grant administrator, who has a scientific background, is to provide overall surveillance and management until the termination of the grant. Ongoing research is monitored primarily through

(1) annual progress reports, which accompany the continuation application for a noncompeting award, (2) publications resulting from the supported research, and (3) personal contact with the grantee. The progress report is the most important instrument in monitoring ongoing research. Progress reports for ongoing research are reviewed to determine (1) significant research developments and (2) departures from the original technical objectives or unusual circumstances that could impede the progress and successful completion of the research.

No written guidelines exist, however, to delineate specific tasks or functions to be done by grant administrators during their review of annual progress reports for ongoing research. Grant administrators said their review of these reports was, for the most part, discretionary, resting on their professional judgment.

Although the grant administrators at the three institutes appeared to be making similar reviews, we could not evaluate the extent or intensity of the reviews, because grant administrators are not required to document them or make formal written comments about the progress of the research.

One institute director said progress reports often do not contain sufficient information to enable a meaningful evaluation of ongoing research. Some progress reports are adequately prepared, while others may lack sufficient technical information to assess progress by grantees. One grant administrator explained that (1) instructions for preparing progress reports are not specific and (2) grantees spend a minimum of time in preparing these reports. Most grant administrators we talked with said the length, detail, and completeness of progress reports vary among grantees.

If NIH grant administrators critically reviewed noncompetitive multiyear research grants with respect to their current scientific merit and research progress, the funds from some noncompetitive grants with poor progress might have been withheld and applied to competing unfunded grant applications. For instance, in NIAID alone, $134,000 could have been directed to other projects in fiscal year 1974 if the funding of five research grants, which ultimately were disapproved by the study sections due to poor progress, had been withheld during the last year of support. Of course, additional funds would accrue the earlier action is taken to withhold grant funds.

TERMINATION OF RESEARCH GRANTS

NIH can terminate research grants under the Code of Federal Regulations (45 CFR 74.114), which states:

> "the granting agency may terminate any grant in whole, or in part, at any time before the date of completion, whenever it is determined that the grantee has materially failed to comply with the terms and conditions of the grant."

Otherwise, NIH can only terminate a grant with the consent of the grantee. A grantee, however, may terminate a research grant at any time.

Failure to comply with the terms and conditions of a research grant includes (1) performing research not originally approved, (2) misuse of Government funds, and (3) the principal researcher leaving the institution to which the grant was originally awarded. We were also advised that NIH cannot terminate a research grant due to poor research progress. As a result, neither the Department of Health, Education, and Welfare nor NIH terminates a research grant or revokes the funding of a research grant, in the interest of the Government, except as stated above.

An HEW legal opinion in 1969 stated that "there is no way to require a grantee not to expend funds already granted * * *" unless the grantee has done something wrong. This document also pointed out "that because of the project period concept, funds unexpended * * * [in one fiscal year] would still be available for expenditure in a subsequent fiscal year within the approved project period." According to an NIH official responsible for policies and procedures for research grants, this means NIH cannot terminate a grant for poor research progress and cannot rescind funds already awarded to a grantee, even though poor research progress is evident. Although NIH may choose not to award future funds under a research grant, he stated NIH cannot reduce the approved project period during which previously awarded funds can be obligated by the grantee.

Under existing regulations, NIH cannot terminate research grant support, although continuation of a project may not reasonably be expected to benefit the public. For example, if a cure for a disease were found or other research breakthroughs occurred, NIH could not end grant support of projects having similar objectives before their normal expiration.

In 1969 NIH attempted to amend the Federal regulations governing research grants to include additional authority to terminate research grants in such cases. It provided that

the Secretary of HEW could terminate a grant whenever he determined that the advance of medical or scientific knowledge, the progress of medicine or health-related sciences, or national health needs were such that a project's continuation could no longer contribute to these purposes.

The intent of the proposed amendment was to recognize that "today's research may be rendered obsolete by tomorrow's discoveries and that the necessity of health-related research varies in accordance with * * * the state of the public health." Although NIH desired to incorporate this provision into the Federal regulations, it was rejected at the secretarial level of HEW in 1970 as being detrimental to the security and stability of grantees. NIH still cannot terminate research grants solely on the basis of public interest or convenience of the Government.

Although the 1969 legal opinion indicated that NIH could withhold future funds from a grantee, grant administrators at the three institutes reviewed differed as to what action they would take regarding poor progress and whether or not NIH had a legal obligation to continue funding a grantee for the entire project period.

For example, one grant administrator at NIEHS said documents sent to a grantee, such as the notice of grant award and policy statements on early terminations, make the institute morally liable to fund research grants for the approved project period. Another official at the same institute believed NIH was legally obligated to continue funding a grantee for the entire project period. However, some grant administrators at NICHD indicated that they would initiate remedial action, such as withholding funding, against a grantee if poor research progress were evident. At NIAID, we were told that leverage would not be used against a grantee once funds had been awarded. Some grant administrators believed the Government's only recourse for these grants was to disapprove them when they again competed for funds.

In contrast to NIH's policy of not terminating research grants, two other research organizations we visited--the Department of the Army Research office and the North Carolina Science and Technology Research Center--will terminate ongoing grants if it is in their best interest. For example, one organization terminated an ongoing grant because it found that two grantees were doing the same research. Officials in both organizations believed that a policy of not terminating research grants, to protect the security and stability of grantees, can only be a disadvantage to the granting organization. Department of Army regulations provide that the Government can terminate a grant and that the grantee will repay the Government the uncommitted balance of all grant funds awarded.

NEED FOR CONSISTENT RANKING OF COMPETING RESEARCH GRANT APPLICATIONS

After the NIH study sections review a competing research grant application and assign a priority score on the basis of scientific merit, the research institutes use either the raw score or normalization techniques for selecting which applications should be funded. Normalization is based on the belief that different study sections have a tendency to consistently assign relatively good or relatively poor priority scores, and the raw scores are, in effect, normalized to offset this tendency.

Because a grant application is funded depending on its relative ranking with applications from all study sections, an NIH advisory committee considered normalization a necessity.

In 1973 the normalization evaluation committee, which evaluated the normalized scoring system, recommended that (1) the normalized score be adopted as the official NIH score and (2) only this score be used for ranking applications reviewed by study sections.

At the time of our review, both the raw and normalized scores were being used to rank research grant applications. Six of the 11 NIH institutes were using normalized scores, while the other 5 were using the raw scores. Even though the normalization evaluation committee pointed out that using normalized scores could not be effective as long as some major awarding components were not using it, NIH has not required its institutes to adopt the normalized scoring system.

The committee also pointed out that, although only a few applications would actually experience a change in funding status, the fact that one application is funded at the expense of another cannot be regarded as trivial. While a grant application might be funded if normalized priority scores were used, it might not be funded if raw scores were used. For example, at NIEHS, raw priority scores are used to rank grant applications for funding. Of 81 grant applications with priority scores 50 points higher and 50 points lower than the cutoff score necessary for funding by NIEHS in fiscal years 1973 and 1974, 6 applications totaling $291,000 were not funded on the basis of raw scores but would have been funded if normalized priority scores had been used. Instead, five other applications totaling $243,000 were funded. Although these five applications had greater scientific merit on the basis of raw priority scores, they had less scientific merit when normalized scores were used as the basis for evaluation.

CONCLUSIONS

NIH diligently tries to insure that the scientific merit of each grant application is assessed before funds are committed to a project.

In our opinion, NIH could better assure that the grants being funded were those with the greatest scientific merit if a system were developed to identify noncompeting grants having less scientific merit than approved unfunded competing grant applications. This system could use normalized priority scores. Once a system is developed to identify noncompeting grants with less scientific merit than approved unfunded competing applications, noncompeting grant funding should not be automatically discontinued, since other factors may make it desirable to continue the funding. We believe, however, that the advantages and disadvantages of continuing to fund such noncompeting grants should be assessed before funds are denied to applications with greater scientific merit.

For such a system to be effective, NIH will also have to require all institutes to use normalized priority scores in funding grant applications for scores to be compared from one year to another. In addition, by permitting institutes to fund grants on the basis of raw priority scores, NIH cannot assure that the biases of the individual study sections are being eliminated and that competing grant applications with the greatest scientific merit are being funded.

Also, the regulations should be changed to permit grants to be terminated in cases when better applications could be funded or the research is no longer of public benefit. In addition the regulations should require the grantee to make reasonable progress as a material condition of grant performance.

Federal regulations preclude the termination of multi-year research grants, except when the grantee has not complied with the terms of the grant. Because of this policy, even if grant administrators were to identify ongoing research they believed to be unnecessary or duplicative, the grants could not be terminated.

We recognize that, except for not being able to rescind funds that were approved in the early part of the grant period, withholding funds and actually terminating funds differ very little. Grant administrators differed, however, on NIH's obligation to a grantee during the grant period. A change in the regulations would clarify and resolve NIH's obligation to grantees.

NIH does not have specific instructions for grant administrators who annually review noncompeting grants. The

type and extent of the review given depends on the individual grant administrators' professional judgments. In addition, NIH does not provide specific guidelines to grantees on what should be included in the annual scientific progress reports submitted to NIH. We believe that formulating such instructions will enhance both the quality and depth of the annual reviews by NIH grant administrators.

We proposed that the Secretary of HEW change the regulations for terminating research grants to permit selective termination of grants when (1) progress is poor, (2) better applications could be funded, or (3) the research is no longer of public benefit. We also proposed that he require the Director of NIH to:

--Develop a system to identify noncompeting research grants with less scientific merit than approved unfunded competing applications and to assess which grants should be funded.

--Establish specific guidelines delineating what should be included in the annual scientific progress report and instructions to grant administrators on how to review noncompeting grants. Written comments on such reviews should be incorporated into the official grant files.

--Clarify the specific authority of grant administrators to withhold funds and disseminate such information to all research grant officials.

--Require all institutes to use normalized priority scores in funding research grants.

HEW COMMENTS AND OUR EVALUATION

HEW generally disagreed with our proposals (see app. I) and stated that implementing them

--would require major alterations in NIH program practices and philosophies,

--would be extremely costly, with little prospect of appreciable benefits, and

--might seriously damage the NIH extramural program.

We believe HEW can implement our recommendations in a far simpler and more effective manner than it has indicated, with little or no additional cost. We continue to believe that proper implementation of our recommendations would result in more meritorious grants being funded.

System to identify noncompeting grants for termination

HEW disagreed with our proposal and offered the following reasons for continuing the present methods for funding grants.

Priority scores are subjective, that is, not exact indicators of the scientific merits of grant applications. Real differences among the scientific merits of grant applications are probably reflected by differences of 30 or more points in priority scores.

Terminating grants early would result in a failure to honor previous commitments and create an undesirable instability within the biomedical community.

The productivity of grants correlates with the original review judgments of the peer review groups. In addition, the approval rate for competing renewal applications is significantly higher than the rate for new grant applications, thus, confirming that the peer review groups screen out most new grant applications not likely to succeed.

Most projects take 2 to 3 years to produce the tangible results needed to evaluate progress, and 3 years is the average duration of a grant recommended by peer review groups. Grantees funded for 3 years submit a renewal application about 1 year before the project period expires. This makes the first 2 years of the research available to the peer review groups for consideration.

To monitor, evaluate, and judge grantee progress with a view toward termination would require the quality, quantity, and variety of expertise now contained within the peer review system used for assessing competing grant applications. The review of ongoing grants by NIH scientists could not be highly detailed because of their heavy workload. Large commitments of staff to evaluate progress are not justified because not that many projects would be identified for termination.

We agree with HEW's comment that priority scores only indicate scientific merit and suggested in the report that priority scores be used to identify noncompeting grants that

should be considered for termination. We further suggested that normalized priority scores would be particularly valuable for this purpose because they measure peer review judgments and can be compared among the various review groups. After such grants are identified, they should be further assessed, not terminated automatically, before funds are denied to applications with greater scientific merit.

In addition, because HEW believes that real differences in scientific merit are reflected by differences of 30 or more points in priority scores, it could use the 30 point difference to identify those grants that should be further assessed. Of the 126 noncompeting funded grant applications we identified as having equal or worse priority scores than competing applications not funded (see p. 6), 28 had priority scores which differed by 30 or more points than some competing grants not funded. Based upon HEW's comments, the scientific merit differed among these 28 grants and the grant applications which were not funded.

During the hearings before the Senate Committee on Appropriations in 1975, officials from several NIH institutes stated that at the proposed budget level, they would not fund lower priority noncompeting grants. According to officials from the two institutes we contacted regarding these statements, they would first consider priority scores in selecting noncompeting grants for withholding action and then consider factors such as productivity and importance of the projects. Those grants with the worst priority scores would probably be the ones from which funds would be withheld. Such use of priority scores in considering noncompeting grants for termination would be consistent with our proposal.

We agree with HEW's statement that cutting off funds for noncompeting grants would result in failure to honor previous commitments, because current regulations restrict HEW's ability to terminate grants. Under current regulations, which we proposed be changed, HEW can unilaterally terminate a grant only if the grantee has materially failed to comply with the terms and conditions of a grant. HEW could change its regulations to (1) clearly require the grantee to make reasonable progress as a material condition of grant performance, (2) permit termination when significantly better applications, as evidenced by priority scores, could be funded, and (3) permit termination where research ceased to be of important public benefit. If the regulations were changed and future grantees were notified that HEW reserves the right to terminate grants in such instances, HEW could redirect the remaining funds to better applications.

Officials in two other research organizations that can terminate grants said this authority had no effect on the quantity and quality of their grant applications and that their organizations receive many more applications than can be funded. The relatively few grants that would be affected by our proposals (using HEW's criteria of when real differences in scientific merit are reflected by priority scores) would not appear to adversely affect the stability of the scientific community.

HEW's comments on the value of the peer review groups for screening out applications not likely to succeed and the productivity of approved grants seem to strongly support our proposal. For NIH not to fund an application of greater scientific merit in the judgment of the peer review groups in favor of an ongoing grant with lesser scientific merit means that NIH is not even considering funding those applications with the highest productivity potential.

HEW's comment concerning the time required to evaluate the progress of a grantee seems to refer to the assessment that would be required of those grants with less apparent scientific merit than the applications that could not be funded. NIH should use the latest information available--such as progress reports or renewal applications submitted before the project period expires--to determine whether the grants should be terminated. As noted by HEW, renewal applications, including the status of the first 2 years of work, are submitted to NIH about 1 year before the project period expires. The peer review groups use this data to approve or disapprove the application and to award it a priority score. Such evaluations do not affect the project period of the existing grant, just the new grant being applied for. Such information could be used to assess whether the current grant should be terminated.

Other information to be considered in terminating a grant is the amount of funds not yet obligated by the grantee which could become available to NIH for funding applications with significantly greater scientific merit.

If NIH would prefer to have the advice of the peer review groups in determining whether to terminate grants with less scientific merit than unfunded applications, we would agree with them. We do not believe our proposal would require a large increase in staff, as stated by HEW, if priority scores were used to screen grants for further assessment. If HEW assessed those ongoing grants with priority scores of 30 points or more than competing applications that could not be funded, only 28 grants in the institutes reviewed would have had to be studied further in fiscal year 1974. This would not appear to place an unreasonable burden on NIH grant administrators or the peer review groups.

Proposal to establish guidelines for preparation and review of progress reports

Since grantees might not have guidelines for annual reporting, HEW agreed to have NIH survey the use of structured progress reports and, if necessary, develop instructions for grantees to use in preparing such reports. HEW also agreed that NIH staff lack formalized NIH-wide instructions for reviewing progress reports and taking appropriate actions on problems. HEW agreed to have NIH develop appropriate NIH-wide instructions.

HEW stated that because of limited staff NIH cannot determine the merit of scientific progress each year for 14,000 projects by reviewing annual progress reports. It can only be assured that the research continues within the scope of the original project and that the investigator has shared with NIH the findings made during the previous year.

HEW saw no need for, or appreciable benefits to be gained from, the scientific staff preparing written comments on their review of progress reports unless they determined that problems exist. HEW further stated that while program staff already document problems they have identified and resulting actions, it will require that grant files be appropriately documented when problems are encountered. Most scientist administrators we contacted said they handle such problems orally. Therefore, the need for NIH to require that grant files be appropriately documented is more significant than HEW indicated.

We have not reviewed the adequacy of NIH staffing but we believe NIH must assure itself that the 14,000 projects involving millions of dollars annually are making satisfactory progress toward the goals specified in the grant applications. To alleviate the workload, NIH could develop a simple form requiring the grant administrator to indicate whether the grantee's progress is excellent, satisfactory, fair, or poor and to provide a short notation explaining the position. This would help NIH officials compare the performance of grantees and could be used with other indicators for determining whether the grant should be terminated.

Proposal to clarify authority of grant administrators to withhold funds

HEW agreed with our proposal and said the Division of Grants and Contracts, Office of the Assistant Secretary for Health, has begun developing guidelines in this area for use throughout the Public Health Service.

Proposal to change regulations for terminating grants

HEW did not agree with our proposal to permit selective termination of grants in cases where (1) there is poor progress, (2) better applications could be funded, or (3) the research is no longer of public benefit. It stated that existing regulations and policies permit the grantor to unilaterally terminate the support of a project when a grantee fails to show satisfactory progress and for other reasons, including a determination that the research is no longer of public benefit. Since NIH must approve at the end of the year the funds a grantee carries over, HEW said NIH can prevent a grantee from carrying over unexpended funds. HEW did not specify under what conditions such a mechanism can be used.

HEW stated that grants do not often need to be terminated. Because of the way grants are approved and funded, HEW said that grants of poor quality or lacking relevance to important health problems are seldom encountered.

We do not agree with HEW's statement that existing policies and regulations provide the authority for NIH to unilaterally terminate a grant because the research is no longer of public benefit. They do not, for example, allow NIH to terminate when recent scientific developments or other events result in research being no longer of public benefit. Further, they do not specifically provide that NIH can unilaterally terminate a grant when progress is poor. The sources HEW cited show that NIH can withhold funds under such conditions but that a grant can be terminated only if the grantee has materially failed to comply with the terms and conditions of the grant. We noted that reasonable progress is not routinely made a material term and condition of the grant award. We believe HEW should revise its regulations to clearly state the conditions under which it can terminate a grant.

We do not believe that NIH can prevent a grantee from spending funds already awarded. As stated on page 9, an opinion by HEW's legal counsel stated that a grantee can expend funds already granted unless the grantee has done something wrong. An NIH official responsible for policies and procedures for research grants said that, although NIH may choose not to award future funds under a research grant, NIH cannot reduce the approved project period during which previously awarded funds can be obligated by the grantee. We believe that termination authority is the only means available for NIH to prevent a grantee from obligating grant funds that were awarded during the budget year.

HEW's comment that grants of poor quality or lacking relevance to important health problems are seldom encountered may very well be true. Once such grants are encountered, however, NIH presently cannot terminate them. In addition, the term "poor quality" is relative. As shown on page 6, 126 funded grants were of equal or poorer quality, based on priority scores, than applications that were not funded; 118 of the 126 had priority scores indicating poorer quality and 28 were in the category which, according to HEW, had real scientific differences.

Proposal to require use of normalized scores

HEW agreed to explore further the use of normalized priority scores in funding research grants. HEW stated that, although the normalization process has been extensively studied in the past, the NIH Grants Peer Review Study Team, recently established by the Director, NIH, to examine all aspects of the NIH peer review system, would further evaluate use of normalized priority scores.

We believe a numerical ranking system is necessary as an aid in selecting grants for funding and that ranking by raw priority scores is not acceptable, because they are awarded by more than one study section. We believe NIH should give priority to studying its process of normalizing priority scores so that one acceptable NIH-wide system for ranking grant applications for funding can be implemented.

RECOMMENDATIONS

We recommend that the Secretary of HEW change the regulations for terminating research grants to clearly require the grantee to make reasonable progress as a material condition of grant performance and to permit selective termination of future grants when (1) significantly better applications, as evidenced by priority scores, could be funded or (2) recent scientific developments or other events result in research being no longer of public benefit. We also recommend that he require the Director, NIH, to:

--Develop a system to identify noncompeting research grants with significantly less scientific merit than approved unfunded competing applications and to assess which grants should be funded. The 30-point difference in priority scores, which HEW considers to reflect real differences in scientific merit, could be used to identify those grants to be further assessed.

--Establish specific guidelines delineat ng what should be included in the annual scientific progress report and instructions to grant administrators on how to revise noncompeting grants. Written comments on such reviews should be incorporated into the official grant files.

--Clarify the specific authority of grant administrators to withhold funds and disseminate such information to all research grant officials.

--Give priority to studying its process of determining normalized priority scores and require all institutes to use it.

CHAPTER 3

TERMINAL REPORTS NOT BEING RECEIVED

Each research grant the National Institutes of Health awards is made subject to the condition that the grantee maintain technical progress and fiscal reports and submit them to the awarding institute on a predetermined basis. In addition, grantees must certify to NIH whether or not inventions have been made as a result of a grant award. NIH requires such reports annually and at the end of the total project period for ongoing grants. The reports submitted at the end of a project period are referred to as terminal reports. At the institutes reviewed, terminal reports were not being received, in part because the institutes were not closely monitoring the submission of such reports.

Although NIH requires the institutes to contact the grantee to obtain delinquent reports, in some cases the institutes were not following this policy and in other cases grantees had been notified but still did not submit a delinquent report. NIH continues to support researchers, even if they have not complied with the conditions of prior grant awards. NIH policy does not prohibit the funding of grantees who have not filed delinquent reports required under other NIH support.

PROBLEMS IN OBTAINING REQUIRED REPORTS

The terminal progress report must include a summary statement of progress made toward achieving the originally stated aims of the grant proposal, a list of the significant results, and a list of publications resulting from the research. According to NIH, the progress report is considered a valuable guide for the institutes in evaluating the work accomplished under the grant. If the terminal progress report is not submitted within 90 days after the termination of a grant, the report is considered delinquent. After 120 days, the respective institute must notify the grantee of that delinquency.

The November 1971 NIH guideline, which addresses terminal reports, states: "A recurring problem in the administration of many NIH grant programs is the delinquency on the part of some grantees in submitting reports required as a condition of the grant award." The same document directs the institutes to insure the submission of such reports.

At the end of calendar year 1974, grantees of at least 321 research grants were delinquent in submitting required reports to National Institute of Child Health and Human Development and National Institute of Allergy and Infectious Diseases. In NICHD, 164 grants that had terminated between fiscal year 1969 and fiscal year 1974 had missing terminal reports. In NIAID, for 157 of 402 grants that had terminated in fiscal years 1972 and 1973, the grantees had not submitted all the required terminal reports. At the time of our review, NIAID officials did not know for how many of the 1974-terminated grants the grantees were delinquent in submitting reports. In addition, a National Institute of Environmental Health Sciences official said the institute did not have a system to insure that terminal reports were submitted as required. Grantees were delinquent in submitting terminal progress reports for all 21 research grants that terminated in fiscal year 1973 and the first half of fiscal year 1974.

Although many grantees of NICHD and NIAID submitted required reports when notified by the institutes, several were notified repeatedly and still did not submit delinquent reports. In many cases, these reports were over 2 years delinquent. At the time of our review, the terminal progress report in both institutes was the one document most often delinquent. For example, of 40 NICHD research grants that terminated in fiscal year 1973, in late 1974, 80 percent of the terminal progress reports were missing while 70 percent of the invention statements were absent from the files reviewed. Of a sample of 28 NIAID grants that terminated between June 1971 and December 1972, 20 grantees were delinquent in submitting the terminal progress report. As of November 1974, 17 grantees still had not submitted such reports.

TERMINAL PROGRESS REPORTS NOT ALWAYS COMPREHENSIVE

Some terminal progress reports submitted by grantees and accepted by the institutes did not contain information on all research conducted during the entire grant period. In some cases, an entire year's research results were not reported.

If a grantee re-applies for NIH support and the application is disapproved, the grant expires. In these cases, NICHD and NIAID accepted the progress report, which accompanied the renewal application, as the terminal progress report, although this report did not cover the entire grant period. Although we were told this practice conformed with NIH policy, no written guidelines or policy statements sanctioned the practice.

According to NIH instructions, the competing renewal application, along with a progress report, must be submitted to NIH for consideration 8 months before the original grant expires for funding not to be interrupted. As discussed previously, the three institutes did not fund approximately 44 percent of competing renewal research grant applications. This rate is similar to NIH's overall rate. The progress reports accepted for these competing renewal research grant applications that are not funded sometimes do not report on research accomplishments for almost the entire last year of NIH support. However, grant administrators in all three institutes said researchers normally use the last year of a research grant to integrate findings and arrive at conclusions. Accordingly, they believed the last year of a research grant was the most important from NIH's standpoint.

To determine the extent that research findings were not fully reported, we sampled 17 terminated research grants for which NICHD and NIAID accepted terminal progress reports. Institute personnel accepted 11 of these reports before the end of the original grant period, although they had been submitted with a competing renewal application. These grantees had not reported the results of the research for the entire project period. For example, one NICHD research grant ended in May 1969, but the terminal progress report was submitted in April 1968 with the competing renewal application. Thus, research results for 13 months were not reported. In another case, grant support ended in May 1973, and the progress report was submitted and accepted in August 1972.

We asked institute personnel why this practice was permitted. They replied that (1) they rely on the grantee to publish research results and, therefore, make the findings known and (2) grant administrators' workloads make it impossible to follow up on every research grant to obtain more complete terminal progress reports.

RESEARCHERS IN VIOLATION OF ONE GRANT FUNDED BY ANOTHER

NIH has no formal system of communicating information within and among institutes about grantees who have not complied with the terms of a research grant by not submitting required reports. As a result, grantees who had not submitted terminal reports under one research grant were being supported by NIH under another grant or contract.

NIH requires that all grantee requests for continuing a noncompeting research grant be accompanied by interim progress and financial reports as a prerequisite for continued

support. Lacking such reports, funding for ongoing research is withheld. However, reporting requirements under a completed grant are not required to be fulfilled as a prerequisite of support under another grant. NIH regulations only state that, if a grantee continues to be delinquent in submitting a terminal progress report, the awarding institute may notify the grantee that it will not fund additional grants in which the researcher is involved until the report is received. However, these regulations do not prohibit a grantee that is delinquent in submitting terminal reports from obtaining another grant.

We randomly selected 15 researchers with expired NICHD grants for which terminal reports had not been submitted to determine if NIH was currently supporting them. Seven were being funded under research grants or contracts by either NICHD or other institutes, although the researcher had not complied with the terms of a previous grant. Only one of the seven researchers submitted a terminal progress report, but even that researcher failed to submit an invention statement. Another researcher did not submit an invention statement but did submit a progress report for part of the grant period when an unfunded competing renewal application was submitted. The remaining researchers did not submit competing renewal applications or terminal progress reports.

In fiscal year 1974, these seven researchers were participating in eight different projects supported by NIH. These researchers' terminal reports from previous grants were delinquent anywhere from 3 to 80 months. NICHD was again funding six of the seven researchers. Total support during fiscal year 1974 for these eight projects amounted to at least $1.5 million. One researcher was being supported by NICHD under a research grant for about $105,000, although he had not submitted reports on two previous grants that NICHD had also funded.

NICHD personnel said no established procedure existed where one institute would routinely be informed of researchers, supported by another institute, who were delinquent in filing terminal reports. In addition, these personnel have not been requested, nor do they systematically inform institute officials, of researchers who have not complied with the terms of a previous grant award.

CONCLUSIONS

At all the institutes reviewed, terminal progress reports and final invention statements were not being submitted as required under the conditions of the grant award. In addition, one institute had no way to readily identify which grants

had delinquent reports or which researchers were responsible for those reports. As a result, the research results accruing under some grants were not being reported to NIH.

NIH policy does not prohibit its institutes from funding researchers who are delinquent in submitting reports. Consequently, NIH is supporting some researchers even though they are violating the conditions of previous research grant awards. Neither the institutes reviewed nor NIH has a system for coordinating and exchanging information on researchers responsible for delinquent reports. Therefore, not funding a particular researcher would be difficult, even if NIH desired to do so.

Because the terminal progress report is the only document required under the grant that summarizes a grantee's research for the full grant period, we believe NIH should establish a system for obtaining the reports at the conclusion of the grant. Future funds should be denied a grantee if the terminal reports are not submitted.

RECOMMENDATIONS

The Secretary of the Department of Health, Education, and Welfare should instruct the Director, NIH, to:

--Require all institutes to more closely monitor the submission of required reports when a grant expires.

--Prohibit the acceptance of terminal progress reports that do not cover the entire period of grant support.

--Prohibit the funding of researchers when they are known to be violating the terms and conditions of previous NIH support.

--Establish an information system capable of exchanging information on delinquent research grant reports among institutes.

HEW COMMENTS AND OUR EVALUATION

HEW agreed that terminal progress reports should be sumitted and that they should cover the entire grant period. HEW did not state what steps it plans to take to implement our recommendations. In addition, HEW did not respond to our recommendations concerning (1) not funding researchers who have violated the conditions of previous support by not submitting terminal reports and (2) the need for a system for exchanging information on such researchers among institutes.

Since we do not know how HEW plans to address the problem, prohibiting funding of researchers who have not submitted terminal progress reports covering the entire period of grant support and establishing a system for exchanging information on such researchers would be effective ways to get all required reports from grantees.

CHAPTER 4

INTRAMURAL RESEARCH

National Institutes of Health scientists conduct intramural research in their own laboratories. The intramural research programs, based on a branch system, are headed by a scientific director or comparable official of the institute who controls and directs the branches by allocating space, personnel, positions, and funds to each branch. The head of each branch reports to the scientific director of the institute. One or more sections, each devoted to specific research areas within a scientific discipline, may be within each branch.

NIH has no formal procedures for initiating most intramural research projects. A number of ongoing projects were terminated because an independent review of the projects showed they were either not related to the institute's mission or their scientific merit was questionable.

LACK OF FORMAL PROCEDURES FOR INITIATING INTRAMURAL RESEARCH

Except for clinical investigations of human subjects and research involving hazardous materials, NIH has no formal policies or procedures for initiating new intramural laboratory research projects. Research projects are not subject to peer review for scientific merit, as required in the extramural grant programs, and the policies and procedures used to start new projects are, for the most part, informal and are established at the discretion of each branch chief.

New research projects in intramural research programs are generally reviewed through discussions between the researchers or principal investigator of a proposed project and the section or branch chief. If the principal investigator is a branch chief, he generally approves his own projects. Although branch chiefs discuss the initiation of research projects with the institutes' scientific directors, in some cases this is not required and projects generally receive no higher approval than that of the respective branch chiefs. None of the institutes reviewed required written justifications or research plans.

Although a few branch chiefs had independently established formal controls over the initiation of research within their own branches, most branches did not require new projects to be subject to peer review before they were begun. However, some branch chiefs said a branch chief might not have the expertise necessary to assess the scientific merit of all projects planned by the researchers they supervise.

According to branch chiefs who had instituted formal procedures, written research plans force a researcher to articulate research goals and methods to be used and provide documentation upon which assessments can be made. One branch chief said formal research plans and peer review of proposals were essential to good management.

In the National Institute of Child Health and Human Development, one branch requires a researcher to submit a written plan before a new research project is initiated. The plan is reviewed and criticized by the researcher's peers within the branch. If this peer group disapproves of the proposed project, it will not be funded. The chief of this branch said the peer review group annually disapproves about six projects after receiving his tentative approval.

In the 3 institutes reviewed, only 3 of the 19 branch chiefs required written plans before the laboratory research project was initiated. Thirteen branch chiefs discussed projects with researchers before they were initiated, while two others said no approval was required. One branch chief required written plans if the resources to be committed were, in his opinion, significant. Of 50 research projects started in fiscal year 1974 at the National Institute of Environmental Health Sciences, 18 were approved after written research plans were submitted to branch chiefs, and 32 were informally approved after discussion with the research scientist.

Most branch chiefs are engaged in research and, therefore, can approve their own research projects. During fiscal year 1974, 10 branch chiefs in NICHD and NIEHS were personally involved in 23 research projects. Eleven NIEHS projects alone cost about $528,000 in fiscal year 1974.

The board of scientific counselors within each institute is appointed by the Director, NIH, under the authority of the Public Health Service Act. The board consists of leaders in basic and clinical research, and its function is to advise the institute director on scientific matters relating to intramural research programs. However, in none of the institutes reviewed were these boards reviewing intramural research projects before they were initiated. One institute director said the board does not review projects before they are initiated, because he believes scientists should have a minimum of outside intervention. Another official felt scientific freedom was necessary for researchers to function. We were also told that the limited number of board members made it difficult to insure the expertise necessary to review all intramural research projects.

The institutes' current methods of initiating intramural research projects could be improved to better insure the allocation of resources to the highest quality of research otherwise attainable. For example, NIEHS officials terminated 14 projects during fiscal years 1973 and 1974; 11 for reasons of low research priority considering available resources. These 11 projects lasted from 2 to 6 years and cost about $1.1 million before they were terminated. At the same institute, the board of scientific counselors reviewed the work of 32 scientists during fiscal year 1974 and found that 5 were doing research (1) not directly related to the institute's mission or (2) of questionable scientific merit. None of the projects terminated had been submitted to peer review and formally approved on the basis of written research plans before they were started.

Although the board of scientific counselors at NICHD generally praised the research efforts reviewed during fiscal year 1974, they criticized the work of some scientists as being of questionable scientific merit. The scientific directors of both institutes generally agreed with the opinions of the boards and followed their recommendations by terminating the projects in question or taking other corrective action such as redirecting the research.

MONITORING AND EVALUATING ONGOING RESEARCH NEEDS IMPROVEMENT

Ongoing intramural research projects were monitored and evaluated through various means, some of which were common to each institute.

The institutes usually monitor intramural research projects informally with, for example, daily contacts and discussions between section and branch chiefs and individual scientists. The institutes were also using research seminars, involving intramural scientists, at which researchers presented their work to their peers for review and discussion. However, the institutes had no formal requirement that these seminars be held nor any prescribed format detailing which researchers would present particular research projects or how often. The seminars operated largely at the discretion of branch chiefs.

Research programs are formally reviewed by the board of scientific counselors at each institute. Officials at NICHD and NIEHS told us that the boards, which meet semiannually, review all intramural research programs within a particular institute every 2 years. The National Institute of Allergy and Infectious Diseases board of scientific counselors reviews all programs within a 4-1/2-year period. Only two boards--

NIEHS and NICHD--however, were reviewing individual research projects or the work of individual scientists. The other board was reviewing overall program direction of the intramural programs.

The NIAID board of scientific counselors was not reviewing ongoing research in detail but in 1974 recommended that a peer review group for intramural research programs be established to evaluate the scientific merit of work done by intramural researchers. A November 12, 1974, NIAID document states that "the Board of Scientific Counselors cannot be regarded as a peer review group and that there are inadequacies in the present NIH system to deal with the problem of allocation of resources * * *." As a result, an NIAID official said that beginning in June 1976, consultants will be obtained on an ad hoc basis to help the board of scientific counselors make peer reviews of individual scientists' work. The consultants will be chosen for their special knowledge in the fields to be reviewed.

As shown in the preceding section, several projects were found to be of low scientific merit or not related to the institute's mission, after the NICHD or NIEHS boards reviewed specific research projects.

CONCLUSIONS

NIEHS, NICHD, and NIAID spent approximately $43.2 million for intramural research in fiscal year 1974. Most research projects were initiated without formal peer review and approval. In addition, some projects were approved by the same scientist who did the research.

Reviews of ongoing research by the boards of scientific counselors indicate that NICHD and NIEHS have funded research of questionable scientific merit and relevance to the institute's mission. At NIAID, reviews of individual research projects were not being made at the time of our review.

In our opinion, peer review of intramural research projects before they are initiated, as well as when they are active, is essential to insuring that NIH's limited resources are most effectively and efficiently used. Although informal mechanisms being used appeared to be beneficial, such systems have not been successful in making best use of research funds.

We proposed that the Secretary of the Department of Health, Education, and Welfare instruct the Director, NIH, to require that written plans for all intramural research

projects be reviewed and approved by a peer review group before research projects are initiated and that reviews be made of specific ongoing research projects. If augmented by ad hoc consultants, the boards of scientific counselors could do this.

HEW COMMENTS AND OUR EVALUATION

HEW did not agree with our proposals and stated that the only justification for changing the management of the intramural research program would be that it was not successful. HEW stated that, by any measurement, the intramural program has produced extremely well. HEW stated that the present system of management is better because it includes (1) a continuing review of ongoing projects, (2) carefully selecting people for employment, promotion, and conversion to permanent status, thus assuring high quality people, and (3) a decisionmaking process concerning the quality and priority of research each time equipment is purchased or a technician is assigned.

HEW also stated that an advantage of the intramural research program is that it provides scientists with the freedom to pursue long-term research without submitting applications. If this advantage were taken away, many top scientists would be lost to other organizations offering better benefits.

HEW stated that the cost of an outside peer review system, plus its destructive side effects, would far outweigh the good to be achieved by weeding out a few lower priority projects. A peer review system would not be able to respond quickly to scientists awaiting approval of their work. HEW also stated that the projects terminated early do not indicate a weakness in the system but a strength.

We did not intend to suggest in our recommendations that

--the quality and productivity of intramural research is lower than research conducted through the NIH extramural program or at any institution other than NIH that conducts biomedical research,

--NIH abandon the management practices it now uses, or

--NIH had to use outside groups to approve a project before it was started (this was mentioned as one possible approach).

We did intend that management of the intramural program be improved by requiring scientists to submit written plans for approval before projects started to avoid research in an area that should not be performed or could be better designed. If NIH wanted to use intramural scientists to review the research plans of their peers, the results would benefit both the researcher and management. For example, one branch chief requires written plans from researchers and that researchers' peers within the branch review and criticize the plans. The branch chief stated that, as a result, some projects were disapproved by the peers after he had given tentative approval. We believe that such a system has merit.

Why would top scientists leave NIH if they were required to document their research plans before they initiate the research? They would be exposed to expert advice from their peers and the quality of the research should be improved. Such a procedure is not required by NIH, but some branch chiefs do this to manage their research work.

We agree with HEW that early termination of certain projects indicates a strength in the review of ongoing research by some institutes. For example, some projects were terminated early when the board of scientific counselors found the research to be of low scientific merit or not directly related to the institute's mission. However, only 2 of the 3 institutes were reviewing specific ongoing projects through their boards. We believe that such reviews should be performed in all institutes.

After considering HEW's comments, we continue to believe our proposals have merit and would benefit research. We do not believe it would be as costly as HEW indicates, since its comments assumed an outside peer review group would be needed. In our opinion, a peer review group of NIH scientists could be used for such a purpose.

RECOMMENDATIONS

We recommend that the Secretary, HEW, instruct the Director, NIH, to require that written plans for all intramural research be reviewed and approved by peer review groups before research projects are initiated and that reviews be made by boards of scientific counselors of all ongoing research projects.

CHAPTER 5

SCOPE OF REVIEW

We made our review at National Institutes of Health headquarters in Bethesda, Maryland, and at National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina. We reviewed 3 of the 10 research institutes existing at the time of our review: National Institute of Child Health and Human Development, National Institute of Allergy and Infectious Diseases, and NIEHS. During our review, the National Institute of Aging, the 11th NIH institute, was established from components of NICHD that had been doing research on aging. These branches of NICHD and related research grants are not discussed in this report.

We contacted officials within each institute as well as at the NIH directorate. We also reviewed the policies, procedures, and implementing regulations concerning intramural research and research grants in the extramural programs to determine how well these programs were being administered. In addition, we obtained documentation from agency files relative to individual research grants and intramural research projects funded in fiscal years 1973 and 1974.

APPENDIX I

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

MAR 17 1976

Mr. Gregory J. Ahart
Director, Manpower and
Welfare Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for our comments on your draft report entitled, "Better Controls Needed Over Biomedical Research Supported by the National Institutes of Health." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

John D. Young
Assistant Secretary, Comptroller

Enclosure

APPENDIX I

APPENDIX I

COMMENTS OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE ON THE COMPTROLLER GENERAL'S DRAFT REPORT TO THE CONGRESS OF THE UNITED STATES ENTITLED "BETTER CONTROLS NEEDED OVER BIOMEDICAL RESEARCH SUPPORTED BY THE NATIONAL INSTITUTES OF HEALTH"

General Comments

The administrative practices of almost any enterprise can be strengthened or improved. NIH is no exception. However, while it is frequently easy to design apparently appropriate improvements, particular care must be taken that instituting such improvements does not irreversibly alter the integrity of the involved organization.

There are two categories of recommendations presented in the GAO draft report. In one category are those which recommend strengthening current administrative practices. We have generally concurred with these recommendations. In the second category are those which recommend major alterations in NIH program practices and philosophies. We do not concur with implementing these recommendations. We believe that implementing them would be extremely costly with little prospect of appreciable benefits and might seriously damage both the NIH extramural and intramural programs.

The National Institutes of Health is recognized internationally as one of the preeminent biomedical research institutions in the world. During Fiscal Year 1975, NIH paid about 38 percent of the cost of all health related research and development performed in the United States. Most of the research funded by NIH was performed under grants and contracts awarded to academic and scientific institutions located throughout the United States and even in many foreign countries. The remainder was performed in NIH laboratories.

During the past two decades of NIH leadership in the fields of medicine and related sciences, the majority of the Nobel Prizes in physiology or medicine have been awarded to United States scientists supported at least partly by NIH. In addition, since 1968, three NIH intramural scientists have received the Nobel Prize.

During this period NIH has established a dynamic and effective relationship with the academic and scientific community which houses most United States biomedical researchers. This relationship has encouraged maximum research productivity with a minimum of administrative direction and control. Under this close working relationship, NIH has been able to support the development of needed advances in basic knowledge and health technology while academic institutions have remained strong in their primary functions. These institutions have also expanded their capacity and

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expertise to conduct biomedical research and have exploited the important role which research plays in enhancing the quality of health professional education.

The high quality of the NIH extramural program has primarily resulted from the intensive, incisive review of grant applications under the peer review system. Under the intramural program, the high quality of the research has resulted from the careful selection of staff scientists who are given maximum freedom to develop their creative ideas subject to continuing review and evaluation by NIH management and their peers from both within and outside NIH.

Following are comments on the specific recommendations presented in the GAO draft report.

GAO Recommendations

The Secretary of HEW should require the Director of NIH to develop a system to identify noncompeting research grants with less scientific merit than approved unfunded competing applications and to make an assessment as to which grants should be funded.

DHEW Comments

We do not concur in this recommendation. (1) Not funding selected noncompetitive grants to provide funds for awarding new applications would be both impractical and wasteful. (2) Attempting to establish and operate the system necessary for identifying ongoing projects for termination would require large staff increases. (3) Cutting off funds for selected noncompeting grants would be very disruptive to the stability of the scientific community. These points are elaborated on in the following.

In view of the unknowns involved in all research ventures, the subjective nature of priority scores, and the loss of resources devoted to approved, ongoing projects if they are prematurely terminated, there appears to be no justification for terminating such projects to provide funds for new projects with better priority scores. To do so would result in a failure to honor previous commitments, would be unsound because projects would be terminated before allowing time for fruition, and would destroy the faith of scientists and their institutions in the stability of Federal biomedical research programs.

Grants are made by NIH to support biomedical research to be performed by scientists employed elsewhere. Each year, over 10,000 research and several thousand other grant applications are submitted to NIH. From these, NIH must select those most likely to succeed and most relevant to its program objectives. To assure that the selection is based upon the best expertise available, NIH established the grants peer review system.

This system consists of many discipline-oriented initial review groups generally comprised of 12 to 18 experts, hired by NIH as temporary consultants, and a national advisory council or board for each Bureau, Institute, or Division of NIH which awards grants. The initial review groups consider the scientific and technical merit of each grant application and render their recommendations and technical commentaries to the appropriate advisory council or board, which provides final recommendations to NIH staff. NIH staff may fund only grant applications which were approved by the councils or boards. This dual peer review system provides a scope and variety of expertise in all fields of biomedical research that NIH could not effectively and economically maintain on its staff.

Members of the review groups make subjective judgments of each grant application. They first judge whether the application has sufficient merit for NIH support. If it does, they recommend approval; if not, disapproval. Therefore, all approved applications merit funding if sufficient funds are available. The reviewers assign numerical values to each application to reflect their perceptions of its merit. Values are assigned on a scale of 1 to 5 with 1 being the highest priority. The assigned numbers are averaged to represent a consensus judgment rather than any one individual's judgment.

The GAO draft report reflects the attitude that the priority score is an exact indicator of quality and that small differences reflect real differences in scientific merit. This is not true. Real differences in merit are probably reflected by differences of 30 or more points in the priority scores. Differences in the scores clustered around the median probably are not significant because they are an average of judgments of individuals with differing opinions and degrees of expertise on the specific subjects presented in the applications. Therefore, we cannot emphasize too strongly that the priority score can be used only as a tool and should not be looked upon as a precise measurement. Clearly, small differences in priority scores should not be used as a basis for terminating an ongoing grant awarded previously in favor of awarding a new one.

Priority scores are only one factor considered by NIH in selecting which grant applications to fund. All applications recommended for approval by the councils or boards merit funding. Many factors influence which approved applications are selected for funding. Among these are: (1) the relative scientific merit of a project, as indicated by its priority score together with the detailed critique of it which was prepared by the initial peer review group; (2) the importance of a particular project to the program objectives of the appropriate Institute or Division; (3) the need to protect previous investments in meritorious ongoing research, as determined by current peer reviews; (4) the need to provide opportunities for new research and researchers to enter the system; and (5) the amount of funds available.

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Under the NIH peer review system the scientific merit of competing research grant proposals and the capabilities of the respective investigators are incisively examined. Decisions to support proposed research are at best "judgment calls," not guarantees of success or even of research productivity.

Most scientists agree that it takes approximately two to three years for most projects to be developed enough to produce the kind of tangible results necessary to evaluate progress. That the average period of support recommended by the peer review groups is about three years attests to this judgment. In most instances, sufficient evidence would not be available in less time on which to make intelligent funding decisions. Because it takes about eight months for a project to be reviewed, an award has to be for about three years if a funding hiatus is to be avoided while a renewal application is under review.

Research does not progress at a constant rate with progress continuing in a straight-line fashion commencing with the first day of funding. During the earliest phases of a research project and up until the period when data analysis is fairly well advanced, there may be no more to judge than the basic considerations that were available to the initial review group. Much research which ultimately proves to be of the highest value in advancing medical technology, such as research on the tissue culture of disease-causing viruses, has been very difficult to accomplish and required many years to bring to fruition.

The GAO report places great importance on the fact that a "considerable" portion of ongoing grants are not funded again when they are submitted for renewal. Because a grant is not funded as a competing renewal does not mean that it should not have been funded originally or that it should have been terminated earlier. If projects were always successful, they would not be research projects. In research areas failures or only partial successes have to be expected. Adequate time must be provided to allow a project to progress to the point when its relative merit and success can be evaluated. If adequate time is not provided, resources devoted to the project would be wasted and those scientific breakthroughs that are realized only near the end of grant periods would be precluded. There is no adequate basis in NIH experience for suggesting that terminating projects after only a year or two to fund new projects with better priority scores is, in fact, realistic.

The review of competing renewal applications is carried out with the same expert review and deliberations as are made when selecting new grants for funding, except that there is also a research record which can be evaluated. Since an investigator working on a project funded for three years must submit a renewal application for competitive review about one year before the first project period terminates, accomplishments during the first two years of the project are available to the initial review groups.

A 1974 study by the Rand Corporation showed that progress on ongoing projects is fully considered by the review groups when renewal requests are reviewed.

The statement on page 7* of the GAO report that 180 approved but unfunded competing renewals did not have sufficient scientific merit to warrant (underlining added) funding by the respective institutes is misleading. If a grant is recommended for approval, by definition, it warrants funding. The fact is that there were not adequate funds to permit their funding. More than 90 percent of the competing renewals were considered of sufficient merit to warrant funding. This is a significantly higher approval rate than exists for new grant requests, confirming that the initial review of new proposals screens out most of those not likely to succeed.

In 1964, the Wooldridge Committee, one of the many outside groups to evaluate the NIH peer review system, reported that the peer review system was about 97 percent accurate. Furthermore, the original findings of the Wooldridge Committee have been substantiated by the 1974 study of the NIH research grant peer review system by the Rand Corporation, which found a very good correlation between the productivity of NIH supported research and the original review judgments.

NIH scientist administrators do use annual progress reports as well as publications to review the progress of grant-supported projects. Generally, progress reports for regular research grants are reviewed primarily to determine whether the research is focused on the originally-approved subject. This review may not be highly detailed because of the heavy workload of NIH scientist administrators.

Grants for centers and some program projects are intended to support long-term, often multidisciplinary research and development. Such activities, involving teams of researchers in both basic and clinical sciences, require longer periods to become fully operational. Accordingly, the NIH Institutes have developed various special procedures for monitoring scientific progress and the quality of the research, involving periodic visits by NIH staff and consultants. workshops of center directors and their research staff, and local advisory groups to oversee center activities. A full NIH peer review is often scheduled at the end of the third year, for a five-year program, to assure that the investigators are told of any need for improvement or modification well before the end of the project period.

If it were to attempt to monitor grantee progress and evaluate and judge that progress with a view toward terminating or withholding funding on less worthy existing projects, NIH would have to institute similar systems within the granting Institutes and Divisions. This would require a

*GAO note: Page number referred to by HEW has been changed to reflect page number in this report.

tremendous commitment of manpower that NIH does not now possess. The manpower dedicated to performing this function would need the quantity, quality, and variety of expertise now contained within the peer review system. Existing extramural scientific staff could not conduct in-depth reviews of scientific progress on the 14,000 active research projects even if it were assumed that such progress was conclusive at the time of review.

Since few projects can realistically be evaluated and judged after only a year's operation, it does not appear that many projects would be identified for termination prior to the end of their project periods. Therefore, large commitments of scientific manpower to attempt to make such evaluations and judgments are not justified. Funded projects should be allowed to run for the periods approved by the peer review committees, unless a project is terminated for cause, such as failure to perform in accordance with the terms of the grant award. This leaves the decision on a project's worth within the peer review system where it most appropriately belongs.

To accomplish NIH extramural research objectives, the institutions in which the research is conducted must be strong and stable. Unilateral termination of or withholding of funds for ongoing projects would create an undesirable instability within the biomedical community, thus destroying the credibility of NIH as a major funding agency, retarding the conduct of research in these institutions, and, most importantly, bringing about an unnecessary tension in our relationships with the scientific community upon which we depend for research progress and medical advances.

GAO Recommendations

The Secretary of HEW should require the Director of NIH to establish specific guidelines delineating what should be included in the annual scientific progress report and instructions to grant administrators on their review of non-competing grants. Written comments on such reviews should be incorporated into the official grant files.

DHEW Comments

We concur in part with the GAO recommendations as follows: For centers and similar large and multifaceted grants, most NIH programs now require very detailed annual progress reports prepared to exacting specifications. These are reviewed in detail. Such grants are often also subjected to surveillance by special program advisory committees or a subcommittee of the appropriate Institute's national advisory council or board. Visits by program staff, often with consultant experts, also track progress and assure that the programs continue to meet the objectives originally approved.

For regular research project grants and any center or other large grants for which there may not be current guidelines for annual reporting or annual staff review, NIH will survey the use of structured progress reports and, if necessary, will develop instructions for grantees to use in preparing such reports.

We agree that there is a lack of formalized NIH-wide instructions given to NIH staff for reviewing progress reports and taking appropriate actions if the material presented in a report indicates that problems exist. Recognizing that individual NIH institutes follow their own procedures in reviewing progress reports, NIH will develop appropriate NIH-wide instructions. However, it must be recognized that research does not progress evenly and that success or failure is not normally achieved within the span of only a few years. NIH scientific staff resources are limited. Therefore, it is not possible for NIH scientist administrators, responsible each year for about 14,000 projects, to determine the merit of scientific progress through reviewing annual progress reports. However, they can assure that the research continues within the scope of the original project and that the investigator has shared with NIH findings made during the previous year.

Preparing written comments each time a progress report is reviewed would create a large workload for an already overburdened program staff. We see no need for or appreciable benefits to be gained from staff preparing such written comments unless they have determined that problems exist. While program staff already document problems they have identified and resulting actions, we will instruct that grant files should be appropriately documented when problems are encountered.

GAO Recommendation

The Secretary of HEW should require the Director of NIH to clarify the specific authority of grant administrators to withhold funds and disseminate such information to all research grant officials.

DHEW Comments

We concur with the recommendation. The Division of Grants and Contracts, Office of the Assistant Secretary for Health, is developing guidelines in this area for use throughout the Public Health Service (PHS).

However, NIH does have certain authority to withhold funds. The GAO report states that NIH does not have the authority to terminate a grant for "poor research progress" and that NIH does not have the authority to terminate a grant on the basis of "public interest or convenience of the Government." We feel that these statements are erroneous. The DHEW

Grants Administration Manual (GAM), chapter DHEW: 1-85 permits the grantor to unilaterally terminate the support of a project when the grantee has "failed to show satisfactory progress" and for other reasons "not necessarily within the grantee's control," such as a determination that the research is no longer of public benefit. Under Title 45 CFR Part 74 and GAM, chapters DHEW: 1-85 and PHS: 1-500, the Director, NIH, may stop the support of a research grant if he determines that the grantee's progress does not materially conform with the terms and conditions of the grant award or the direction of the research has been so altered that it no longer is health-related or of public benefit.

The report also states that "Although NIH can withhold funds from a grantee for the remainder of an approved project period, it cannot rescind funds that were approved but unexpended for the earlier part of the grant period." NIH cannot, except for cause, rescind funds that have been approved but unexpended during the budget period for which they were awarded. However, since NIH must approve all carry-overs of funds from one budget period to the next, it can prevent a grantee from carrying over unexpended funds. When NIH approves carrying over unexpended funds it generally uses them to reduce future awards.

GAO Recommendation

The Secretary of HEW should require the Director of NIH to change the regulations for terminating research grants to permit selective termination of grants in cases where (1) there is poor progress, (2) better applications could be funded, or (3) the research is no longer of public benefit.

DHEW Comments

We disagree with the recommendation. We feel that the existing research grant regulations, together with established DHEW and PHS policies, are sufficient to deal with those situations where it is appropriate to stop the support of a project.

Also, we do not believe that situations dictating the need for terminating a grant occur very often within NIH's extramural program. By limiting most research projects to about three years of support between competitive reviews, by applying incisive peer review to all research grant applications, and by carefully selecting for funding only approved projects having potential benefit, NIH assures that research of poor quality or lacking relevance to important health problems is seldom encountered in its grant activities.

GAO Recommendation

The Secretary of HEW should require the Director of NIH to require all institutes to use "normalized" priority scores in funding research grants.

DHEW Comments

We concur in the GAO recommendation to the extent that we will explore further the matter of using normalized scores. Between 1971 and 1973 an NIH Committee reviewed and developed a normalization procedure for assigning priority scores which was put into effect for one year. Under the assumption that all fields of science are essentially of equal merit, the normalization computation is intended to adjust for assumed variations in the behavior of different review groups in rating applications. Because this assumption is only partly true, the NIH Executive Committee for Extramural Affairs elected to retain the use of raw scores but to also make normalized scores available as an aid to the institutes. No priority score system, whether normalized or not, can replace staff and councils' consideration of each application in the "gray zone" where normalization may impact upon awarding decisions.

Although the normalization process has been extensively studied in the past, we will explore it further by referral to the NIH Grants Peer Review Study Team which was recently established by the Director, NIH, to examine all aspects of the NIH peer review system.

GAO Recommendations

The Secretary of HEW should direct the Director of NIH to (1) require all institutes to more closely monitor the submission of required reports when a grant expires, (2) prohibit the acceptance of terminal progress reports which do not cover the entire period of grant support, (3) prohibit the funding of researchers when they are known to be in violation of the terms and conditions of previous NIH support, and (4) establish an information system capable of exchanging information on delinquent research grant reports between institutes.

DHEW Comments

We partly concur in the GAO recommendations, as follows:

We agree that required terminal reports should be submitted. The DHEW Grants Administration Manual, chapters PHS: 1-462 and 1-42, provides policy guidance on grant closeout requirements and delinquent grantee reporting procedures, respectively. We plan to take steps to ensure the timely submission of terminal progress reports.

We agree with the recommendation that terminal reports should cover the entire grant period.

GAO Recommendations

The Secretary of HEW should direct the Director of NIH to require that written protocols for all intramural research projects be reviewed and

approved by a peer review group prior to the initiation of research projects and that reviews be made of specific ongoing research projects. If augmented by ad hoc consultants, the Boards of Scientific Counselors could perform this function.

DHEW Comments

We do not concur in the recommendation that intramural research projects be reviewed and approved by a peer review group prior to the initiation of research projects. We believe that the present internal system of control over intramural research is more economical, efficient, and timely than a peer review system similar to or duplicative of the system used for awarding grants would be. The quality of the work of NIH intramural scientists as well as the priority of their ongoing research projects is already routinely reviewed and evaluated at several levels within the NIH system.

Operating the type of formalized peer review system used for awarding NIH grant funds is very costly in several ways. NIH spends considerable money in consultant fees and travel costs for the hundreds of outside experts it uses to review and evaluate grant applications. Much high-level scientific manpower is spent in reviewing and evaluating applications, making needed site visits to prospective grantees, and meeting three times yearly to decide on the acceptability of grant applications and set priorities on those judged acceptable.

However, a system had to be established to assure that only meritorious science is supported under the NIH grants mechanism. To meet this need the peer review system has evolved as the best mechanism for defining and administering a quality extramural biomedical research program which is spread over a wide geographic area. However, it is not the best mechanism for administering an ongoing intramural scientific program. The intramural research program of NIH is largely self-contained in the geographic sense and can avail itself of a highly appropriate but different mechanism for defining and administering a quality in-house research program, namely continuing review and evaluation, carried out both formally and informally by the scientists' colleagues and superiors.

Only if the operating NIH intramural system were not providing highly productive, high level research results would it appear desirable to consider imposing on it such a costly mechanism as outside peer review. The NIH intramural program, however, by any method of measurement yet devised, has produced extremely well, resulting in very high quality scientific endeavors.

Added to the above is our fear that imposing an outside peer review system could have serious destructive effects on the NIH intramural research program. NIH has two assets that help it hold first-class

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scientists. They are (1) a relative freedom to pursue research activities, without submitting formal research grant applications and (2) generally good research facilities. Universities typically can outbid NIH on salaries, fringe benefits, and professional status. If NIH had to put its scientists through the same procedures that university scientists go through to obtain grants, we could lose many of our top investigators. If we lost many top investigators because they no longer had the administrative and continuity benefits present at NIH to offset other benefits available elsewhere, many young scientists who come to NIH to work with and learn from such investigators would not come here. If these occurred, NIH's prestige would rapidly decline and we would have destroyed a scientific system and organization that has been the heart of biomedical research and training in the United States.

The following paragraphs discuss in more detail our position on these GAO recommendations.

Intramural NIH scientists are under the control and supervision of carefully selected section and laboratory or branch chiefs who continually review and evaluate their work. The laboratory or branch chiefs report to and are under the control of their institutes' scientific directors who report to their institute directors and also to the NIH Deputy Director for Science, both individually and collectively, at semi-monthly Scientific Directors' Meetings.

Every time a technician is assigned or a piece of equipment purchased a decision is made on the quality and priority of the research. The real reviews and decisions are made within the area of allocating scarce resources. When projects do not measure up, such resources are withheld or negotiated downward.

Each institute has a Board of Scientific Counselors, comprised of scientists from outside NIH, which reviews in an advisory capacity the institute's intramural research programs. These Boards were created to bring to bear on the various intramural programs the direct views of experts from outside NIH. The Boards, in essence boards of visitors, were intended to (1) advise Institute Directors and their Scientific Directors on research program designs, emphases, and directions and (2) review and generally evaluate scientific work under the research programs.

NIH has considered conducting peer reviews of proposed research projects by the members of the Boards of Scientific Counselors. However, we feel that this is an inappropriate function for them. We believe that they can best be used to provide evaluations of ongoing research programs and that they should indicate their views on how such programs fit into our overall mission.

The continuing review and evaluation mechanism, such as used at NIH, has gained long standing acceptance in industry, commerce, and academe because it is:

(1) continuous rather than episodic;

(2) immediately responsive in allocating resources in the continuous competition for the limited budget and space available; and

(3) dynamic and produces viable and effective feedback.

An important contrast can be made between the extramural peer review process and the intramural review and evaluation process. In the former, there is only periodic opportunity for assessment of the value of research work being proposed. In the latter, there is close supervision and continuous assessment by superiors, colleagues, and associates during the conduct of the research itself. Therefore, we believe that the continuing review and evaluation mechanism is the best method for supporting and maintaining the quality of the NIH intramural program.

Within intramural NIH, the selection and hiring process is an important part of the management and direction of research. For this reason the NIH intramural program has developed "add-on" personnel systems, such as the Staff Fellow program. These programs stand at the heart of the continuing review and evaluation mechanism described above. These programs provide an opportunity to assess and measure the intellectual excellence of young investigators prior to conferring tenure in the form of a permanent appointment.

In the case of staff fellows, who serve in a non-tenured capacity for four to five years, NIH has the opportunity to evaluate their productivity over an extended period. If a staff fellow does not develop as anticipated or his research interests are not congruent with those of his Institute, his appointment can be terminated. Thus, NIH's granting of tenure carries with it the commitment to support a scientist's research so long as he is productive. Civil Service and Commissioned Officer regulations limit the ability to terminate the employment of an individual. Therefore, NIH puts great emphasis on the initial selection process. Recommendations for conversion to permanent status are made to the Deputy Director for Science by the Scientific Directors at their semi-monthly meetings. Such conversion is a highly selective process. Only about one-third of the staff fellows who completed their terms of appointment in Fiscal Year 1975 were converted to permanent status.

Another control over the quality of NIH scientists is the review process followed when a permanent scientist is proposed for promotion to the next higher grade or to an administrative rank, such as Section Head or Laboratory Chief. Promotional decisions are discussed and debated carefully

at the semi-monthly meetings of the NIH Scientific Directors, who then recommend action to the Deputy Director for Science.

The Scientific Directors take these responsibilities very seriously since they provide the major elements of quality control across the intramural programs of the various institutes and contribute to the equity and comparability among equivalent scientific ranks at NIH. In preparation for bringing their nominations to the Scientific Directors' meetings, individual Scientific Directors thoroughly study and investigate the qualifications of the scientists in question. Inputs into a decision on nominating an NIH scientist either for conversion to permanent status or promotion include discussions with his section and branch chiefs; an evaluation of his publications of original scientific articles; an examination of feedback from reviews conducted by the appropriate Board of Scientific Counselors, which may have been supplemented by ad hoc consultants; a review of his performance in staff seminar presentations; and a review of other materials which may have been solicited, such as letters from eminent scientific leaders outside NIH.

The NIH system of reviewing the quality of its scientific staff places great responsibility on each Scientific Director, but this is precisely his responsibility as a Federal Science Administrator. To the degree that the intramural scientific programs have been of high quality and productivity, this must, in large part, be attributed to the dedication, sensitivity, and judgment of the Scientific Directors.

At NIH, a key aspect of research management is the high level of the scientific expertise of section chiefs, laboratory or branch chiefs, and institute scientific directors. Research seminar programs also serve an important quality control function at NIH. Such seminars of assembled NIH scientists may be likened to the site visits made in connection with grant applications. In addition to continuing in-house reviews, the boards of scientific counselors, bolstered as needed by ad hoc experts, periodically review in detail the research programs of intramural scientists.

We do not believe that, as stated in the GAO report, projects being terminated indicates a weakness in the NIH system, rather partly its strength. By the very nature of research, not all projects will be successes. Failures, or less than total successes, have to be expected. When such projects can be identified and terminated, the system must be working well. However, several of the projects cited in the report were terminated because of shortages of resources or to bring certain programs into balance with others, not because of lack of scientific excellence. In the face of limited resources we must continually review our ongoing studies to insure that the highest priority and most promising efforts are carried out. It is not unusual that potentially good projects are shelved because of the lack of resources. Terminating projects does

not mean that they were not worthy of the funding they had already received. Unfortunately, budget constraints which prevent funding worthwhile, potentially promising projects or programs can cause gaps in our scientific knowledge. Often very good projects may be shelved because the long-range benefits could not be perceived during the initial phases. Given additional resources we would fund work in many additional research areas.

NIH provides an environment in which outstanding scientists can pursue the long-term basic and clinical research needed for solutions to the more difficult scientific problems. This is an environment consisting of an unparalleled number of scientists in many disciplines in a facility with enormous technological depth and availability of specialized equipment.

One of the major virtues of the NIH intramural research program has been its ability to provide the environment under which scientists can pursue important long-term research studies without having to wrap them up prematurely because of arbitrary, external deadlines imposed by limited-duration grants. Such studies would be difficult to pursue under the extramural system. Examples of these are the long-term studies on the so-called "slow-virus" diseases and longitudinal studies on an aging population. Such types of research require prolonged commitment of resources and a faith that eventually an innovative research plan will result in useful knowledge. The intramural program has been able to exploit these opportunities because of the flexibility in the way we administer the research organization and the fact that NIH scientists are protected from the large time commitment to raising money which increasingly faces scientists in the extramural area.

The only justification for materially reorganizing the management of NIH's intramural research program would be that it has not been very successful. However, the NIH is widely regarded as providing high scientific quality research influencing very importantly the directions of biomedical research elsewhere. It serves as an important information and consultation center and as an important training institution for young scientists in basic and clinical research. Many of the leaders at the NIH and in biomedical research in academic institutions get their start in NIH's laboratories.

By implication, the GAO recommendations suggest that the quality of extramural grant projects is better than that of intramural research projects and that, if intramural projects were to undergo the extramural peer review procedure prior to their initiation, the quality of such projects would be improved and would be similar to that of grant supported research.

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In fact, the general quality and productivity of the NIH intramural research programs compare very favorably with research conducted extramurally, as determined by several objective parameters by which publications can be assessed.

Computer Horizons, Inc., has developed a weighted formula for measuring the influence of articles published in scientific journals. Using this formula it has developed and analyzed data of publications by NIH scientists in the biomedical literature.

Computer Horizons reported that, by one measure, NIH's publications have a higher influence per publication than any other major institution in the United States except Harvard. The average publication weights for the 15 leading institutions are:

(1) Harvard University, 31.2,
(2) NIH, 29.8,
(3) University of Wisconsin, 28.2,
(4) Yale University, 27.3,
(5) Johns Hopkins University, 24.9,
(6) University of Pennsylvania, 24.8,
(7) Columbia University, 24.8,
(8) Stanford University, 24.2,
(9) University of Washington, 23.5,
(10) University of California, 22.0,
(11) New York University, 21.9,
(12) State University of New York, 20.5,
(13) University of Michigan, 19.8,
(14) University of Minnesota, 19.8, and
(15) Mayo Foundation, 18.8.

Furthermore, its analysis of 240 institutions showed that there is no other substantial institution that has an influence per publication figure higher than NIH except the Rockefeller University, which has an extraordinarily high publication weight of 42.

Another way to measure intramural NIH productivity is to compare the percentage of the members in the 6 societies of the Federation of American Societies for Experimental Biology who are intramural NIH scientists (3.22%) with the percentage of papers from the United States which were authored by intramural NIH scientists and were published in various journals. In 1973, the NIH figures were:

(1) for the 1,000 biomedical journals studied, 3.43%;
(2) for the 20 biomedical journals that have the highest influence per publication, 5.12%;
(3) for the 20 biomedical journals with the highest influence weight, 5.78%;

(4) for 12 biomedical review journals, 7.49%;
(5) for the Journal of Biological Chemistry, 7.50%;
(6) for Analytical Biochemistry, 8.46%;
(7) for the Journal of Experimental Medicine, 9.16%; and
(8) for the Biophysical Journal, 10.13%.

Therefore, NIH appears to be pulling more than its proportional weight in papers published in the more prestigious and influential scientific journals.

NIH has considered duplicating within the intramural research program the peer review system used to evaluate research grant proposals. We concluded that imposing such a system on the intramural program would not be practical. It would mean that all intramural research projects would have to be reviewed in advance by panels of outside experts. Getting enough interested and competent outsiders to review all the projects of a full-time staff the size of NIH's would be extremely costly, both in terms of the consultant fees and travel costs NIH would have to pay and the time the consultants would have to spend making such reviews. Furthermore, we believe it would be impossible to administer a research program like ours if decisions on support had to be made by outside panels. The resources we deal with are budgeted positions, space, and money. They cannot be awarded and withheld with the flexibility of dollars in research grants, nor can decisions on projects be made without regard for the impact of those decisions on the careers of the scientists in a full-time, largely tenured service. Finally, and most important, an outside peer review of projects would so change the intramural program that it could no longer provide scientists with what is the unique virtue of intramural research, the opportunity for real continuity of effort over long time periods.

Normally, the greatest continuing cost element in research today is the salaries of the research teams. We have difficulty envisioning an outside peer review system which could respond so quickly that it would not result in intramural investigators and their staffs awaiting approval to perform their work. We believe such a system would be neither desirable nor feasible.

We have concluded that the manpower and money costs of imposing an outside peer review system, plus its destructive side effects, would far outweigh the good to be achieved by weeding out a few lower priority projects. There is no good evidence to indicate that the savings anticipated from pre-screening intramural research projects would offset the considerable costs involved in utilizing such a procedure in a research institution the size of NIH. These costs would involve both the expenses associated with making the reviews themselves as well as the adverse impact on NIH staff caused by delays in initiating projects and uncertainties about their research support.

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NIH is a first-class research institution. Its excellence has been recognized with three Nobel prizes in the past few years. The high level of quality will be difficult to maintain during a time of no growth or actual cutbacks. It can be done with strong and intelligent leadership. We do not see how mandatory outside peer review of scientists or their intramural research projects would benefit. We believe that the GAO recommendation, if put into effect, could have serious effects on the NIH intramural research program. We do not believe that approval of a written protocol prior to initiation of an intramural research project would be a desirable procedure to impose upon NIH intramural projects. Such a procedure would impose an unnecessary degree of formality and rigidity to the ongoing internal management of the intramural research program. It would possibly, by stifling work in particular areas, actually diminish the uniqueness and quality of the intramural program.

PRINCIPAL HEW OFFICIALS RESPONSIBLE FOR ADMINISTERING ACTIVITIES DISCUSSED IN THIS REPORT

	Tenure of office	
	From	To
SECRETARY OF HEALTH, EDUCATION, AND WELFARE:		
David Mathews	Aug. 1975	Present
Caspar W. Weinberger	Feb. 1973	Aug. 1975
ASSISTANT SECRETARY FOR HEALTH:		
Theodore Cooper (note a)	Feb. 1975	Present
Charles C. Edwards	Mar. 1973	Jan. 1975
DIRECTOR, NATIONAL INSTITUTES OF HEALTH:		
Donald S. Fredrickson	July 1975	Present
R. W. Lamont-Havers (acting)	Feb. 1975	July 1975
Robert S. Stone	May 1973	Jan. 1975
DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES:		
Richard M. Krause	Nov. 1975	Present
John R. Seal (acting)	Aug. 1975	Oct. 1975
Dorland J. Davis	Oct. 1964	Aug. 1975
DIRECTOR, NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT:		
Norman Kretchmer	Sept. 1974	Present
Gilbert L. Woodside (acting)	Sept. 1973	Sept. 1974
DIRECTOR, NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES:		
David P. Rall	Mar. 1971	Present

a/Acting from Feb. 1975 until May 1975.