Appendix B

Background Materials: Grants, Contracts, and Peer Review

The funding mechanisms of the extramural programs of the National Institutes of Health (NIH) have an impact on the various technology transfer activities. In large part, this impact is due to the way in which the extramural projects are selected and administered. This appendix describes the awarding process for grants and contracts, the two primary funding mechanisms. In addition, it presents a review of recent studies of the peer review system and a discussion of various grant mechanisms.

Research Grants

The main types of research grants are research project grants, program project grants, and center grants. According to the NIH publication NIH Extramural ***Programs*** (52), they may be distinguished as follows:

- Research project grants are awarded to an institution on behalf of a principal investigator to facilitate pursuit of a single scientific focus or objective in the area of an investigator's interest and competence. Institutional sponsorship assures the NIH that the institution will provide facilities necessary to accomplish the research and will be accountable for the grant funds. A research grant may occasionally be awarded directly to an individual who has access to adequate facilities and resources for conducting the research . . .
- Program project grants are awarded to an institution on behalf of a principal investigator for the support of a broadly based, often multidisciplinary, long term research program with a particular major objective or theme, A program project involves the organized efforts of groups of investigators who conduct research projects related to the overall program objective. The grant can provide support for the projects and for certain shared resources needed for the total research effort. Each project supported under a program project grant is expected to contribute to the overall program objective.
- Center grants, awarded to institutions on behalf of a program director and a group of collaborating investigators, provide support for long term, multidisciplinary programs of research and development. The distinction between program project and center grants is that center grants are more likely to have a clinical orientation and are usually developed in response to announcements of the specific needs and requirements of [an institute or division]. Center grants support programs in critical health problem areas including: research and development; demonstration of advanced techniques for the diagnosis, treatment, prevention, or control of disease; education; and other related nonresearch components. Although center grants may support both the projects and the "core" or shared resources, in some instances, only "core" costs are provided under the center grant, and project support must be requested through the project or program project mechanisms.

Research grants may be used to pay the salaries of personnel, the purchase of equipment and supplies, travel, publication, the institution's direct costs, and other purposes directly associable with the research. The award also includes reimbursement for indirect costs, or overhead, to the investigator's institution. Establishing an overhead rate that is equitable to both the government and the institution continues to be a problem (114).

Grant applications submitted to NIH are received centrally in the Division of Research Grants (DRG). This Division, one of the research and support divisions at NIH, has most of the responsibility for administering the grants applications review program, although each institute's participation in the process is essential with respect to grants awarded out of its individual appropriation. DRG collects, stores, analyzes, evaluates, and retrieves management and program data needed in the administration of these programs. It also provides advisory and consultative services to grantees relating to grant policy and management matters.

The most important function of DRG, though, is to screen all incoming grants applications, determine the relevance of each application to the overall mission of NIH, **and assign acceptable applications to an appropriate initial review group** (IRG, or more commonly "study section") for scientific peer review **and to an appropriate institute for funding review.** The two reviews, referred to as the "dual review system, " occur sequentially. DRG does not assign the applications for review arbitrarily. Instead, assignment to an IRG is based on the match between the subject of a proposed research project and the review responsibilities and scientific expertise of the IRG's members; assignment to an institute is based on the institute's legislatively mandated program responsibility. Ap-

placations may be assigned to two institutes at once if the subject matter is pertinent to the program responsibilities of both. Should the primary institute decide not to provide funding, the other institute may consider it.

Depending on the type of research proposed, the first level of scientific and technical merit review is by an IRG located either within DRG or within an institute. IRGs within DRG are called study sections. Currently, there are four groups of study sections—Behavioral and Neuroscience Review, Biomedical Sciences Review, Clinical Sciences Review, and Special Review—which contain 55 review groups representing at least sO disciplines. IRGs in the institutes are usually multidisciplinary and are constituted to review more complex program project and center grant applications.

The IRGs are composed of 10 to 15 highly qualified nongovernment consultants selected on the basis of their recognized competence and achievements in their respective research fields. An NIH health scientist administrator serves as executive secretary of each group. The executive secretary reads each application and assigns it to two or more members of the IRG best qualified to judge the application in detail. When assessing the scientific and technical merit of an application assigned to their IRG, the members consider several factors, including: the training, experience, and research competence or promise of the investigators; the adequacy of the experimental design; the suitability of the facilities; and the appropriateness of the requested budget to the work proposed.

IRG members, who serve up to 4 years per appointment, meet three times a year to review applications. At the meetings, the applications are recommended either for approval, disapproval, or deferral for more information (which may be obtained using outside assistance or site visits) by majority vote. In addition, for applications recommended for approval, each member of the IRG individually and privately assigns a numerical rating that reflects a personal evaluation of the scientific merit of the proposed project. The executive secretary then combines these ratings into one priority score and prepares a written summary of the considerations, including a project description and critique, a recommended budget, an explanation of the IRG's recommendation, and notations about any special points. Both the priority scores and the summaries are then forwarded to the appropriate institutes and other awarding units for the second level of review.

Each of the awarding units has a national advisory council or an equivalent unit that reviews and determines approval of grant applications before a grant can be awarded. These councils are mandated by law, and some have minimum levels placed both on the number of times they must meet each year and on the number of members they must have. Members include authorities in scientific and health fields directly related to the program interests of the institute or division, as well as lay people noted for their interest or activity in national health problems. Except for the National Cancer Advisory Board (NCAB) and the National Library of Medicine Board of Regents, the council members are selected by the Secretary of Health and Human Services and serve 4-year terms.

The councils review grant applications in a broader context than the IRGs, because their recommendations are based not only on the IRG scientific and technical merit evaluations, but also on the needs of NIH and the missions of the individual institutes, the need for initiation of research in new areas, the degree of relevance of the proposed research to the missions of the institutes, and other policy issues. The council recommendations are forwarded to the institute director for funding. The priority scores assigned to the grant applications by the IRGs serve as a virtually inviolable guide to the advisory councils and to the awarding units in their decisions regarding the order in which the approved grant applications will be funded. However, while the councils can not change the priority scores, they can recommend that an approved application be classified to be funded or not to be funded based on program relevance. The projects approved by the councils are usually chosen according to rank until the budget is obligated. An approved grant application is not assured of funding, because there are almost always more eligible applications than available funds. A disapproved application, though, can not be funded.

R&D Contracts

The NIH publication NIH *Extramural Programs* (52) states that research and development (R&D) contracts:

> . . . are awarded to nonprofit and commercial organizations to foster and direct scientific inquiry toward particular new areas of research and development and to utilize advances in knowledge and technology to search for solutions to specific questions. Contracts are conducted with close NIH direction and monitoring; negotiations afford the contracting parties flexibility in establishing the details of their relationship at the outset of the contract work.

The same publication describes several types of R&D contracts: 1) research contracts focus on a specific research problem that has been identified by an

NIH component and requires central direction, control, and management, such as clinical trials of new and existing therapies; 2) development contracts are awarded for projects to produce substances, devices, systems, or other approaches to diagnose, prevent, treat, or control diseases; and 3) demonstration contracts are awarded when NIH desires to direct, or at least control closely, opportunities to demonstrate the feasibility of applying new advances to individual or community situations to solve certain health problems, such as cancer control programs. Contracts may also be awarded for certain types of research support services or resources (e. g., data processing, collection and distribution of materials needed to conduct R&D) as well as for conferences and workshops to facilitate scientific communication and evaluation.

The contract mechanism offers more universal competitive opportunities to all types of scientific sources. It is used by the Government to fulfill its specific program objectives. Thus, because the areas of work to be undertaken are already defined, offerors can compete for a commonly understood objective, and contract proposals received are evaluated within the framework of criteria announced to all competing sources.

Each awarding unit (institute or division) has developed slightly different methods to satisfy its research needs. The basic mechanism used to develop requests for proposals, to review contract applications, and to evaluate the progress and outcomes of contract products, though, are similar enough to be summarized in a general description. The scientific staff members within a given institute, with assistance from standing committees or ad hoc advisory groups, develop a research project description and plan. The concept of the project is then evaluated by a scientific review group composed largely of non-Federal advisors, in compliance with the law that mandates peer review for NIH contract projects. Next, the proposed project is released as a request for proposal (RFP), which specifies the terms, conditions, and provisions for the requested contract. The RFP appears in several appropriate publications, including the Commerce Business Daily and the NIH *Guide for Grants and Contracts.*

Contract proposals, submitted in response to an RFP, undergo several stages of review. First, they are reviewed by the institute's contracting officer and then by a scientific review group consisting mainly of nongovernment scientists with expertise in the relevant area. Their recommendations are sent to a contract review committee composed of senior program staff from the funding institute. During this review, the various elements of the proposals involving costs are examined by Government cost analysts in conjunction with technical personnel. Applicants determined to be in the "competitive range" have an opportunity to further defend or clarify their proposals in written or oral discussion with the contracting officer or senior program staff. Once the applicants have made their "best and final" offer, the remaining applications are reevaluated via further negotiations in order to determine the one to be funded. The ultimate objective of such negotiations is to reach a balanced equitable agreement. Occasionally, unsolicited contract proposals are received by DRG. They are forwarded to an appropriate institute, and if relevant to the institute's needs, are reviewed in a process similar to that for solicited proposaIs.

Once awarded, the progress and products of contract research are under the supervision and review of the contracting officer at the funding unit. Informal and formal procedures are used to monitor the performance of the contract project. A major difference between contract research and grant (and intramural) research, at least in theory, is that contractors are required to provide an end product based on specifications established by the institute before the research begins. With grant-supported and intramural research, requirements for production of a given outcome are generally much looser. Another difference between the funding mechanisms is that advisory councils or boards are not required to approve contract awards as they are mandated to do for grants. Nevertheless, they are usually quite involved in the awarding unit's research planning process, which includes the allocation of resources for both grants and contracts.

Recent Studies of the Peer Review System

The peer review mechanism, being at the heart of the grant-in-aid award system, has been the subject of a number of recent studies. The General Accounting Office (GAO) (27) compared the operation of the peer review and progress monitoring systems at NIH and the National Science Foundation (NSF). In general, GAO found the NIH procedures better. However, GAO's concern was not, as they stated, with the quality of the review or the fairness of the review, but with the process of the review. Examining the quality of the scientific review is a different problem and exceeded the resources available to GAO at the time.

NIH conducted a review of its own peer review system in the late 1970's (50,51). Perhaps, not unexpectedly, they found the system to do a good job. Recommendations on which action have been taken

were those directed at the mechanics of the system. "A few recommendations were made regarding substantive issues of peer review but action on these was deferred by the NIH Director pending further study" (27).

The President's Cancer Panel has announced that it will host discussions in various cities around the country during 18 months to begin early in 1982. The purpose of those meetings is to hear opinions about the submission and review of grant applications at the National Cancer Institute (NCI) (announcement of Dr. Armand Hammer at the NCAB meeting, Feb. 1, 1982).

NSF placed a contract with the National Academy of Sciences (NAS) for a study of their peer review system. Two reports from that study have been published. The first (15) appeared in *Scientific American.* It reported:

1. A high correlation between reviewer ratings and grants awarded.
2. Absence of a high correlation between grants awarded and previous scientific performance of the applicants. ("This result was unexpected.")
3. That reviewers from major institutions did not favor applications from other major institutions.
4. That length of the scientific career of the applicant had no strong effect on review ratings.
5. Low or moderate correlation between reviewer ratings and:
   - prestige rank of applicant's current academic department;
   - academic rank;
   - geographic location;
   - NSF funding history over last 5 years; and
   - place of Ph. D. training.

The second paper, published in *Science (14)* reported rather more alarming results. Seventy-five applications from three different NSF programs that had been reviewed by the NSF peer review system were subsequently reviewed by other groups of peers. Surprisingly (to some, at least) and dismayingly (to more, perhaps), the ratings bestowed on about 25 percent of the applications by the two review groups differed enough to have affected whether or not the application would have been funded. The disagreements went both ways. In some cases, the NSF peer reviewers' ratings that resulted in a decision to fund an application was reversed by the second group. In other cases, an NSF review rating that would have meant no funding was changed sufficiently that the second rating would have resulted in funding. The two review groups did not differ in scientific accomplishments or esteem, and both appeared to be equally "peer." The authors of the study concluded that the "luck of the draw" in reviewers has a significant impact on how an application fares.

The NSF peer review system typically uses some four or five scientists to review an application. The luck of the draw might seem more of a factor in that system than in an NIH study section with 15 scientists. The authors of the paper about NSF review reached no conclusion about the importance of the luck of the draw in the NIH system. However, it is the practice in NIH study sections to assign each application to a primary and a secondary reviewer. If those two reviewers differ from the other study section members, and the others have read the application less thoroughly, luck of the draw may be important. The probability that members read less carefully applications on which they are neither primary nor secondary reviewers is almost a certainty. Applications typically run to several score pages, and each study section considers an average of 80 to 100 applications at each of its three-times-a-year meetings.

One expert contacted by OTA in the course of writing chapter 6 of this report has served on both NIH and NSF review groups. He found the NIH system to be more thorough and that the active discussion of applications at study section meetings produced better reviews. He thinks that prejudice, favoritism, and ignorance of a subject show up in study section discussions and that this assures the applicants fairer consideration.

Some suggestions have been made to institute an appeals system for applicants whose rating is less than they think they deserve. Currently, the disappointed applicant must prepare another proposal. The time necessary to write a new application plus the time for another review (typically about 9 months from NIH's receipt of the application to a decision to fund or not to fund) means a long period with no decision. Furthermore if a preexisting grant expires before a new one is secured, part of the scientist's research program may have to be shut down.

An instititute advisory board can suggest that an application be sent for a second review to a second study section. If the applicant has a current grant that will expire during the second round of study section review, the board suggestion results in an extension of the preexisting grant at its current funding level until the second review cycle is complete. The second benefit to the applicant is that rereview of an existing application means that it is unnecessary to prepare a new application.

Some generalizations can, of course, be made. Scientists who have been successful in the current review system view it more favorably that those who have not. There are opportunities within the system for reviewers to play favorites or to discharge ani-

mosities, but **none of the experts that** OTA talked with offered specific examples. **The NIH system works well** (27) **in keeping applicants informed of what is happening to their proposals and of** reasons for the decisions that are made.

Typically, criticisms of the peer review system are countered by arguments similar to those used to counter criticisms of democracy: Yes, there are problems, **and, indeed, the system may be as bad as can be imagined, but it's better than anything else. OTA'S conversations with experts generated four pointed criticisms of the NIH peer review system.**

1. **The research proposals that project 2, 3, or more years into the future are not worth the paper they are written on.**
2. **Narrowly focused, "can't miss" applications receive better scores than applications that are broader and, if successful,** more important.
3. "Peers" on study sections are not scientifically equal to the applicants, and sitting on a study section allows second-rate scientists opportunities to steal ideas from applicants.
4. **The NIH rules that a scientist can serve only one** term on a study section is resulting **in study section membership growing younger and younger. Younger scientists are not familiar with the difficulties and costs of running large-scale laboratories.**

Directed at points 1 and 2 were comments that good investigators plan carefully, obtain results, and follow up leads. Narrow, carefully focused proposals are most accurate in predicting results. By analogy, it may also be that the authors of such applications are least-well prepared to generate or recognize unpredicted leads and follow them **down unexpected courses. Of course, a breakthrough finding might occur in either broadly or narrowly focused research, but rapid exploitation is thought to be more likely in the former case.**

Suggestions were made that NIH (and NSF) consider attaching greater weight to records of past accomplishments and less to projected research projects. Both the study of NSF peer review (15) and the GAO study of both NSF and NIH peer review (27) drew attention to the relatively small weight **given to past performance. The NSF study, as has been mentioned, regarded that finding as "unexpected."**

Published papers, which experts in the field, such as study section members, will have read anyway, provide a measure of scientists' accomplishments. Reliance on past performance, as judged from the scientific literature, should reduce the workload on reviewers, and at the same time, permit ranking of the applications. A grant supports a scientist's research efforts; how the scientist has done in the past is a guide to future production.

An immediate problem with "review" concentrating on past performance is how to judge the just-beginning investigator. Some experts expressed the opinion that "new" investigators are now treated differently from "established" ones. Study sections may be willing to take more of a chance on the new investigators. NIH estimates that one out of four scientists who are awarded an NIH research grant receives one and only one grant. This 25 **percent includes both one-time grantees who do not submit another application ("dropouts") and individuals who resubmit and do not achieve a fundable priority score.**

Opinions were expressed to the OTA staff that reviewers tend to judge more harshly applications that involve risk in the sense that an experiment may fail to produce the result that is predicted. Discussions about this point emphasized that poorly prepared or poorly thought through applications were not to be favored. "Fishing expedition" applications, which describe experiments to be done with little description of expected results and scanty information about the interpretation that will be placed on results were not held in high regard. On the other hand, concern was expressed that applications that posit a number of possible outcomes, even those prepared by well-regarded scientists, may not be given high grades in comparison to near repeats of already completed studies in which results can be predicted with greater certainty. The past production of good results and proper interpretation of those results, in the eyes of some, are a better guide to the future than proposed research.

Experts who discussed peer review with OTA staff pointed out that greater reliance on past performance would reduce concern about the third point mentioned above. Applications that describe the future in general terms would be a less rewarding source of intellectual plunder.

Finally, greater reliance on past performance would provide more time for research on the part of applicants and reviewers. The application could be shorter and require less preparation. The reviewer would have less to read.

Comments Made to OTA About Various Grant Mechanisms

The research project grant in support of an individual researcher's activities is the backbone of NIH research activities and is seen as the essential element in research support. In addition, some experts con-

tacted by OTA expressed great favor for program project grants. The arguments made for such support was that it concentrated the talents and experiences of several individuals on a single project. The common goal is seen as producing a research whole greater than its parts. Review of program projects includes a site visit by a study section members and NCI staff, and that activity was seen as making for better reviews.

The responses concerning center grants varied. Several experts think that center grant applications are so large and complex as to be almost impossible to review. There was also concern that poorer quality research and researchers might shelter inside center grant support. On the other hand, centers—because of their size and complexity—allow some research projects that cannot be supported by other mechanisms.

One respondent suggested that center grants might be made to exceptional scientist-administrators in much the same way as the Max Planck Institutes in Germany are funded. The center director would be responsible for hiring staff, reviewing and approving research efforts, and the productivity of the center. At the end of the grant support period, the center's performance would be judged by its publications and reputation. Such an approach would eliminate the cumbersome and, some suggest, ineffective review of center grant applications. It would also represent a giving-up of authority by NCI.

Conclusions. —The peer review and extramural research system, being fundamental to the success of NIH, have been studied, examined, and discussed. The result of almost all of the investigations has been confirmation that the system works. There have been no suggested alternatives. A contrast to that generally favorable conclusion is the finding about the "luck of the draw" in the review process.