Chapter 5

Technology Transfer at the National Institutes of Health

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Chapter 5

Technology Transfer at the National Institutes of Health

INTRODUCTION

Obviously, the involvement of the National Institutes of Health (NIH) in technology transfer goes beyond research and development (R&D), as evidenced by its support for activities such as evaluation, demonstration and control programs, information dissemination, and consensus development conferences. What is not obvious, though, is the extent to which NIH should be involved in technology transfer or what its role should be in relation to other public and private organizations. These are questions that need to be addressed by policy makers. Yet they cannot be answered unless the *actual* extent to which NIH contributes to technology transfer, both formally and informally, is known.

The purpose of this chapter is to provide an overview of technology transfer at NIH. OTA finds that a broad spectrum of activities is actually part of the transfer process, although not necessarily formally recognized as such. First, a general overview, including a brief history, of NIH's authority and mission in the area is presented. Next, current activities relating to technology transfer—R&D, clinical trials, consensus development conferences, demonstration and control programs, information dissemination, relationship with industry, and training—are described.

It is beyond the scope of this report to cover all activities at all institutes. Thus, this chapter will present the overview, and the next two chapters will discuss the National Cancer Institute (NCI) and the National Heart, Lung, and Blood Institute (NHLBI), the two largest, in depth. At the actual level of operation, the differences among the semiautonomous institutes often exceed the similarities.

ACTIVITIES

General Overview: A Changing Role

The rapid growth of NIH between its beginning as a multiinstitute organization in 1944 and the mid-1960's was in contrast to the limited Federal involvement in other activities in the health field at that time. Faced with its broad mission on one hand and the tradition of limited Federal involvement on the other, NIH made at least three key policy decisions during that period affecting its current and future role in technology transfer (111).

First, the decision was made to foster the development of biomedical research programs in medical schools and their affiliated hospitals. An effect of this decision was to expose medical students to research in the basic medicaI and clinical sciences and give them sufficient understanding, tools, and motivation to master and use new knowledge as it was developed. Second, the decision to adopt training grants as the main mechanism to foster the training of clinical investigators was made. As a result, clinical departments of medical schools were strengthened, and the link between research and practice was developed. The third major decision was to concentrate on building the research program, while minimizing service-oriented activities, such as disease control programs. At the time, NIH was concerned only indirectly with the diffusion and adoption of new technologies.

Until 1965, NIH was oriented as a supporter of basic bioscience research organized around categories of diseases. This organization satisfied those who were results oriented (7). However, in

1965, Congress authorized the Regional Medical Program to be administered by NIH. This program was designed specifically to facilitate the application of medical advances by using regional medical centers as a focus of technology diffusion and information dissemination (7). According to Tilson, et al. (111), this legislation "epitomizes the emerging congressional interests in making the NIH responsible for the practical application of new knowledge as well as its development."

While not generally considered successful, the Regional Medical Program signaled the start of new trends in congressional interest and action for NIH. The National Cancer Act of 1971 and the National Heart, Blood Vessel, Lung, and Blood Act of 1972 mandated demonstration and control programs in the two institutes. The 1974 cancer amendments mandated a President's Biomedical Research Panel, which, in its study of biomedical and behavioral research at NIH and the Alcohol, Drug Abuse, and Mental Health Administration, covered service-oriented and applied activities. The President's Panel research and report began to focus attention on the overall appropriate role and effectiveness of NIH as a "transfer agent" in the continuum from fundamental research to accepted medical practice (107). Congressional hearings on NIH requested testimony on the subject several years in a row (116,117). And throughout this period, Congress provided special funding for selected elements of knowledge application and dissemination in several of the institutes (97).

Simultaneous with increasing interest in technology transfer activities by Congress was increasing interest by leaders at NIH. In 1975, the mission of NIH was stated as a broad continuing one:

> . . . to advance the health and well being of man through (I) enlarging knowledge and understanding of the normal and pathological processes of the human body, and (2) developing ways in which the providers of medical care can safely and effectively intervene to prevent, treat, or cure diseases and disabilities. NIH pursues this mission through supporting:
>
> - biomedical research and development, including in some instances, demonstration and control;
> - research training;
> - development of research resources; and
> - communication of findings and results of research **(56).**

The mission essentially implies knowledge development without a similar commitment to *knowledge applications.* As a result, there have been several unsuccessful attempts to broaden the statement (114).

In written form, the mission appears to remain the same; there is no corresponding statement in the 1981 Research Plan (58). However, even when the preceding statement was written, and certainly continuing today, there has been considerable attention by NIH to increasing its technology transfer activities. One of the most important results has been the establishment of the Office for Medical Applications of Research in October of 1978. This office will be described further separately.

Another result has been an increasing written focus on transfer activities, including evaluation, consensus development, demonstration and control programs, etc. In 1979 and 1980, the Director of NIH focused attention on technology transfer issues by circulating a document that conceptualizes NIH-sponsored research as a flow of basic science research to its transfer in the field. There are four steps in the process: 1) conducting of basic science research (science base), 2) development of technologies for solving specific problems and testing their application in the field (application), 3) building of a consensus among the scientific community regarding a solution's feasibility followed by its transfer to the field for demonstration (transfer), and 4) training of researchers to ensure the development of basic science research (training) (17). In *1980,* the percent of total NIH resources allocated to each respective area was 77, 12, 5, and 5 (57).

An additional example of focus on technology transfer is a compilation of the statutory authority for all of the institutes in the areas of technology assessment and transfer *(60).* This document demonstrates there is ample authority for transfer activities (as defined in this report) in all institutes. However, the extent of the activities writ-

ten in the laws, and therefore specially funded varies widely from institute to institute. For example, the sections covering the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) mandates such programs as diabetes research and training centers, arthritis demonstration projects, and an information and education center for digestive diseases. The National Eye Institute (NEI) has no similar legislated directive.

R&D and Technology Transfer

R&D activities are not generally considered to be part of technology transfer. However, these activities are very much a part of the technology transfer process—basic research provides the knowledge base, and applied research and development use the knowledge to solve specific problems. In many cases, the solution to the problem is a technology. As noted throughout this report, technologies in the medical area are drugs, devices, medical and surgical procedures used in medical care, and the organizations and support systems within which such care is provided.

Thus, the relative amount of resources devoted to each of the "categories" of R&D—basic research, applied research, and development—affects technology transfer. In addition, the grant awarding process at NIH affects technology transfer. These areas will be discussed below.

Resources for R&D

Table 8 illustrates the amount of resources in 1982 targeted to basic research, applied research, and development activities. In total, R&D activities comprise 94.2 percent of the entire NIH budget. Of the R&D activities, 53.7 percent is for basic research, *35.2* percent is for applied research, and 11.1 percent is for development.

Among the individual institutes and divisions, these figures vary widely. For instance, the National Institute of General Medical Sciences (NIGMS) will spend *86.5* percent of its research dollars on basic research, 12.3 percent on applied research, and only 1.2 percent on development. In contrast, NCI will target 34.2 percent to basic research, 43.3 percent (the bulk) to applied research, and 22.5 percent to development. And, NHLBI's distribution mirrors the total NIH distribution. The variances among the institutes are not surprising, if the missions of the individual institutes are considered. NIGMS exists to support research and research training in the sciences basic to medicine. However, NCI has a number of broader goals in addition to its cancer research, including cancer control programs, and collecting and making available information on cancer *(48).*

Table 8.—NIH R&D Activities, 1982 (dollars in millions)

	Basic research	Applied research	Development	Subtotal	Training	R&D facilities	Total
NCI	$ 327.9	$ 414.5	$215.4	$ 957.8	$ 23.4	$ 5.4	***$ 986.6***
NHLBI	302.4	166.3	61.1	529.8	29.8	—	***559.6***
NIDR	32.1	34.6	0.8	67.5	4.5	—	***72.0***
NIADDK	219.7	109.0	20.9	349.6	18.6	—	***368.2***
NINCDS	167.0	77.8	12.5	257.3	8.6	—	***265.9***
NIAID	143.8	61.5	22.0	227.3	8.6	—	***235.9***
NIGMS	252.9	36.0	3.5	292.4	47.4	—	***339.8***
NICHD	111.2	91.5	14.7	217.4	8.9	—	***226.3***
NEI	64.4	52.3	7.2	123.9	3.5	—	127.4
NIEHS	53.7	42.1	3.9	99.7	6.6	—	106.3
NIA	46.8	29.3	3.4	79.5	2.4	—	81.9
DRR	96.7	76.2	10.6	183.5	0.7	—	184.2
FIC	8.5	0.6	0.1	9.2	—	—	9.2
NLM	3.1	5.7		11.7	32.7	—	44.4
OD	9.2	9.0	:::	20.8	1.8	—	22.6
B&F	—	—	—	—	—	9.9	9.9
Total, NIH	$1,839.4	$1,206.4	$381.6	$3,427.4	$197.5	$15.3	$3,640.2

SOURCE: Division of Financial Management, Office of the Director, National Institutes of Health

In theory, the resources expended on applied R&D are part of technology transfer, albeit at the beginning stages of the process. It could be said, then, that NIH allocates 46 percent of its research dollars to technology transfer, defined broadly. There are several problems with this figure, however. First, the figure does not provide a measure of the transfer *process,* that is, how or whether the basic research results move into applied research and so forth. Second, and perhaps more important, essentially all of NIH's activities, including its more formal transfer activities (e. g., consensus development conferences, demonstration programs) are included in the basic, applied, and development figures. These other activities are actually part of the later stages of the transfer process, and this fact is not reflected. Finally, a related problem is that definitions of basic research, applied research, and development mean different things to different analysts, and the criteria used to classify activities differ from program to program and from year to year (118). An example of this is the comparison between the breakdown in table 8 and the percentages reported for 1980 in the previous section—77 percent of resources for the "Science base," 12 percent for "Applications," 5 percent for "Transfer," and 5 percent for" Training. "

Grant Awarding Process

The "dual review system" grant awarding process at NIH, described in appendix B, affects technology transfer in at least three ways. First, the initial review, or peer review, is a mechanism intended to assure that the work being supported is of excellent quality and is likely to produce results. For basic research, the form of the results is uncertain. The important point, though, *is that new knowledge that can be transferred will be created.* For applied research and development, the results are often medical technologies to be transferred. There have been numerous reviews of the peer review system, and its critics have raised questions regarding objectivity and practice in accord with contemporary standards of public agency behavior (114) and the degree to which a different review group would make the same recommendation (12,13). Nevertheless, most reviewers believe strongly that no better system assures such high quality (12,97,114).

Second, the use of advisory councils or boards to approve actual grant awards is intended to assure that the proposals funded are relevant to the priorities of the awarding unit. Thus, when technology transfer activities are a priority for a particular institute, its advisory council can affect whether these activities actually occur. This is particularly true for NCI, NHLBI, and NIADDK, who have a number of mandated formal transfer activities. Third, the members of the initial review groups and advisory councils are generally not government employees, but instead hold full-time positions elsewhere. In the case of the initial review groups, the members are well-known scientists. In the case of the advisory councils, the members are either experts in fields related to the institutes' missions or public members. In each case, the members affect technology transfer by informally reporting on NIH research activities to their "outside" worlds.

Clinical Trials

As one of the most important tools for evaluating the efficacy and safety of medical technologies, clinical trials are a critical component of the technology transfer process. A clinical trial, as described more fully in chapter 4, is a scientific research activity undertaken to prospectively define the effect and value of prophylactic, diagnostic, or therapeutic agents, devices, regimens, and procedures applied to human subjects (114). These trials provide the basis for the testing and orderly application of fundamental research knowledge prior to its general introduction into the health care system. When utilized, they are part of the ideal technology transfer process, because they provide the evidence to prevent the premature diffusion of technologies into medical practice. Similarly, they may be used to accelerate the transfer of new technologies. In an ideal transfer process, clinical trials are done after development research but before demonstration and control projects.

NIH is the single largest supporter of clinical trials in the United States (92). Its involvement in clinical trials in fiscal year 1979 was $136.1

million; this amount represents 4.3 percent of its total obligations that year (49). Since most trials last longer than a year, completion of the trials underway is estimated to cost at least three times the funds spent in 1979.

The early 1970's was the biggest time of growth in clinical trial activity. Between 1971 and 1974, four of the 11 institutes (NCI, NHLBI, the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), and NEI) nearly tripled their obligations for major clinical trials (85). In 1975, support for clinical trials at $110 million represented 5 percent of the total budget for that year. Thus, although the increase in total funds between 1975 and 1979 was nearly 24 percent, the rate of increase in clinical trials has decreased. In response to this, NIH noted that such a statement does not take into account the increase in efficiency with which clinical trials are conducted.

Tables 9, 10, and 11 illustrate NIH support for clinical trials during fiscal year 1979. Table 9 delineates clinical trial investment by institute and by type of support. Table 10 shows the number of clinical trials conducted by institute and by

Table 9.—Amount of NIH Support for Clinical Trials Active in Fiscal Year 1979, by Institute for Type of Support

Institute	Extramural support				Intramural Support[b]	Total amount of Support
	Grant	Contract[a]	Grant and contract	Total		
NIH	$47,304,588	[c] $75,738,766	$1,954,960	$124,998,316	$11,161,800	$136,160,1 16'
NEI	3,141,547	5,378,262	—	8,519,809	85,800	8,605,609
NHLBI	4,006,736	50,933,477	159,788	55,100,001	1,423,500	56,523,501
NIAID	2,435,341	3,827,597		6,262,938	234,000	6,496,938
NIAMDD	1,927,658	5,226,975		7,154,633	1,085,500	8,240,133
NICHD	3,074,448	556,296		3,630,744	552,500	4,183,244
NIDR	221,977	557,672	—	779,649	999,050	1,778,699
NINCDS	1,786,449	439,000	—	2,225,449	435,500	2,660,949
NIGMS	225,750	—	—	225,750		225,750
NCI	30,484,68F	8,819,489	1,795,172	41,099,343	6,345,950	47,445,293 [c]

[a] Contract includes interagency agreements without intramural support.
[b] Intramural support includes intramural support in combination with interagency agreements
[c] One trial did not report amount of support

SOURCE: National Institutes of Health, 1979 *Inventory of Clinical Trials.*

Table 10.–Number of Clinical Trials Supported by NIH in Fiscal Year 1979, by Institute for Type of Support

Institute	Number of trials supported extramurally				Number of trials conducted-intramurally	Total number of trials
	Grant	Contract[a]	Grant and contract	Total		
NIH	592	212	11	815	171	986
NEI	20	3	·	23	3	26
NHLBI	3	13	1	17		20
NIAID	80	34	—	114	:	120
NIAMDD	30	22	—	52	15	67
NICHD	24	6	—	30	2	32
NIDR	2	11	—	13	13	26
NINCDS	17	3	—	20	20	40
NIGMS	1	—	—		—	1
NCI	415	120	10	54:	109	654

a contract Includes interagency agreements without Intramural support, Two trials were supported mostly by contract with some intramural support.
b Intramural S$_{uppo}$fl includes intramural support in combination with interagency agreements. One trial was supported mostly by Intramural support with some contract support.

SOURCE: National Institutes of Health, 7979 *Inventory of Clinical* Trials

Table 1 I.–Number and Amount of Support for NIH Supported Clinical Trials Active in Fiscal Year 1979, by Institute for Type of Intervention

Institute	Total trials supported in fiscal year 1979[a]		Type of Intervention					
			Therapeutic[a]		Prophylactic[a]		Diagnostic[a]	
	Number[b]	Amount[b]	Number	Amount	Number	Amount	Number	Amount
NIH	666	$112,847,367	494	$50,540,964	118	$58,875,778	53	$3,170,625
NEI	26	8,605,609	22	4,890,194	2	3,415,997	2	299,418
NHLBI	20	56,523,501	10	9,726,605	10	46,796,896	—	—
NIAID	120	6,496,938	57	2,992,347	39	2,697,064	24	807,527
NIAMDD	67	8,240,133	60	7,680,072	4	246,798	3	313,263
NICHD	32	4,183,244	16	2,532,054	15	1,629,175	1	22,015
NIDR	26	1,778,699	7	779,051	17	776,871	2	222,777
NINCDS	40	2,660,949	35	1,565,020	2	959,429	3	136,500
NIGMS	1	225,750	—	—	1	225,750	—	—
NCI	334	24,132,544	287	20,375,621	28	2,127,798	18	1,369,125

[a]Trials in cooperative groups not included.
bone trial did not report amount of support. One trial did not specify type of intervention.

SOURCE: National Institutes of Health, 1979 Inventory of *Clinical Trials.*

type of support. From these tables, it is clear that the average expenditure per trial ranged widely, from $2.8 million for NHLBI to $54,000 for the National Institute of Allergy and Infectious Diseases (NIAID). The NIH-wide average is $138,000. The tables also indicate that the mechanism of support varies from institute to institute. Most clinical trials are conducted extramurally; the only exception is at the National Institute of Dental Research (NIDR). Of the extramural types of support, the bulk of dollars was spent on contracts. This was true for five of the nine institutes supporting trials. However, the greatest number of trials were conducted by grant; only NHLBI and NEI had a greater number of contracts. It seems reasonable that the largest trials be conducted by a mechanism which allows greater control by the institute.

It is interesting that the two largest sponsors of trials—NHLBI and NCI—use such different mechanisms to fund them. Although the NCI trials are currently being converted to cooperative agreements, there will still be great differences between the mechanisms and processes. Chapters 6 and *7* discuss clinical trials at these institutes in depth.

Table 11 delineates expenditures for trials by three functions of technology: therapeutic, prophylactic, and diagnostic. For the entire NIH, the greatest amount of funds was spent evaluating prophylactic interventions. Therapeutic technologies were close behind, and diagnostic technologies followed at quite a distance. The view of the total NIH picture is somewhat misleading, since most of the trials and most of the dollars were spent on therapeutic technologies if NHLBI figures are excluded.

An earlier OTA report, *Assessing the Efficacy and Safety of Medical Technologies (85),* reported on the expenditures for clinical trials by functions of technology in 1975. At that time, clinical trials investigating therapeutic technologies were predominant. Furthermore, a majority of the trials were conducted to test drugs either in isolation or in combination with another type of technology (with the bulk tested in isolation). More than *300* of the trials tested cancer chemotherapies, while only 25 evaluated surgical procedures. Few trials examined the efficacy of screening or early diagnosis, or primary prevention technologies. Except for the reversal in the relative ranking of trials of prophylactic technologies and of therapeutic ones (caused by the large increase in NHLBI trials of prophylactic technologies), it appears that the findings of the earlier OTA report are still accurate.

NIH's interest in clinical trials does not end with supporting them. Upon their completion, major attention turns toward presentation of the basic results in scientific and professional journals. The primary means of disseminating the analysis of a trial to the research community is publication of the results. Dissemination also occurs through workshops, conferences, and pro-

fessional societies (42). Other examples of interest in clinical trials can be found at the institute level. At NCI, the Board of Scientific Counselors has a Clinical Trials Subcommittee to make recommendations relating to all aspects of the trials (66). If the results of the trials on a particular technology do not lead to a clear decision about its application in clinical practice, NIH has a mechanism to synthesize the evidence for dissemination. This mechanism, the consensus development conference, will be discussed in the next section.

There are several issues that pertain to the role of clinical trials at NIH. One concerns the appropriate amount of investment in clinical trials. This is a difficult issue to address. Clearly, greater and greater amounts of resources are being expended for clinical trials, although the amount as a percent of the total budget has decreased in recent years. On the one hand, investment in clinical trials is extremely important and potentially remunerative since it can prevent new unproved procedures from finding their way into medical practice (and into reimbursement by the Federal programs) (114). However, trials are in many cases quite costly. And, the demand for trials appropriately leads to more trials. Yet resources devoted to trials must necessarily be balanced with more fundamental investigations of etiology and pathophysiology of disease, the foundation of our ability to prevent and treat disease and the source of new *clinical* hypotheses requiring testing (42).

Another important issue relates to the funding mechanism used to support clinical trials—grant v. contract v. cooperative agreement. Differences between these mechanisms include the amount and type of review on the proposal, the initiation of the idea for the study, the timing of the application process, the amount of control and monitoring which can be conducted by the institutes, and types of end products required (100). In addition, the mechanism may affect the technologies selected to be tested. For grants, the scientific merit of the proposal (rather than its topic) determines award selection. Although there are specific policies that attempt to define the differences between the mechanisms, the distinctions between them are becoming blurred. As noted earlier, the various institutes utilize different mechanisms. Thus, particularly because of the current drive to change grants to cooperative agreements (at least at NCI), the effect of the different mechanisms on trial outcomes should be carefully evaluated.

A related issue is the impact of the budget constraints, in combination with a drive to stabilize the number of competing grant awards, on the ability to begin new clinical trials. While the budget of NIH has not yet suffered the cuts that many other Federal programs have felt and will feel in fiscal years 1981, 1982, and 1983, the rate of budget increase has certainly not kept up with inflation. At the same time, there has been an effort to stabilize the number of competing grant awards to be made each year to eliminate erratic changes in likelihood of meritorious projects being funded. This search for stability, while potentially alleviating one serious problem, has created certain tensions in other areas, notably in the institutes' ability to begin new clinical trials. For instance, in the *1983-85 Research Plan* published in December 1981 (58), NHLBI states that:

> . . . the most severe impact [of stabilization] will be felt in clinical trials and targeted research, funded under the contract mechanism, where no new efforts can be implemented in 1980-1982. . . The contract mechanism is best suited to fund clinical trials, and rapid advances in research and developments in cardiovascular and pulmonary treatment techniques necessitate clinical evaluation at a time when no new contracts can be awarded.

Other institutes with smaller budgets and less efforts in the clinical trials areas, such as the National Institute of Child Health and Human Development (NICHD), NIAID, and NIDR, make similar statements.

Office for Medical Applications of Research

Background

In response to the congressional *concern* with the systematic assessment and transfer of new technologies, the Director of NIH conducted an extensive study of the potential NIH role in this

area. The study resulted in a paper entitled, "The Responsibility of NIH at the Health Research/Care Interface, " dated February 28, 1977 (80). This paper defined the problem and the role of the individual institutes and divisions in technology transfer, and expressed the need for a central office to coordinate the existing activities. It took the current status a step further and indicated a need for a formal systematic approach for assessing health care technology and disseminating clinically relevant research findings to the medical practice community and the public.

On May 11, 1977, the Director of NIH initiated a request to the Department of Health, Education, and Welfare (HEW) to establish the Office for Medical Applications of Research (OMAR). This request spelled out the need for new procedures of transferring knowledge that would promote effective community application. The primary mechanism proposed for this task was the development of consensus along with the consideration of the implications involved in the application of the technology. OMAR was informally established in the Office of the Director in September 1977, and was officially created by the Assistant Secretary for Management and Budget of HEW on October 4, 1978 (59).

As published in the Federal Register, OMAR'S functions are as follows *(59):*

1) Advises the Director, NIH, and his senior staff, and provides guidance to the bureaus, institutes, and divisions on medical applications of research;
2) Coordinates, reviews, and facilitates the systematic identification and evaluation of clinically relevant NIH research program information;
3) Promotes the effective transfer of this information to the health care community and through the [National Center for Health Care Technology (NCHCT)] to those agencies requiring such information;
4) Provides a link between technology assessment activities of the bureaus, institutes, and divisions of the NIH and the OHT (Office of Health Technology of DHEW): and
5) Monitors the effectiveness and progress of the assessment and transfer activities of the NIH.

In June of 1980, the Director of NIH appointed a committee to review the activities and mission of OMAR. The review also covered related areas, including technology assessment at NIH, effective coordination of medical applications of research activities at NIH, and the value of a central NIH focus and an apparatus for advice and oversight. A report was issued on September 24, 1980 (59). The committee's findings are generally applicable today, since OMAR has changed little in structure since its inception, although the processes of the office have become more formal. Indeed, the major change affecting the office has occurred outside of NIH: NCHCT was not funded in fiscal year 1982, and thus, OMAR'S activities formerly conducted in coordination with NCHCT are either conducted by OMAR alone or not conducted at all. Thus, the sections of the committee's report concerned with the former NCHCT do not apply. At issue today is whether some of the former NCHCT'S activities should now be acquired by OMAR. This issue will be discussed further.

Structure and Role

OMAR is a relatively small office, with five professional and four support staff members. During its first 2 years, the program cost approximately $700,000 per year. In 1981, $1.2 million was the approximate figure, exclusive of staff costs and evaluation studies (83).

OMAR'S Advisory Committee, consisting of representatives from the various bureaus, institutes, and divisions of NIH, assists OMAR in achieving its goals. Its members and the OMAR staff meet monthly to discuss, determine, and plan consensus development activities and to exchange information relating to other NIH involvement in assessment of biomedical technologies (90). The committee has been in existence since August 1977, even before the formal establishment of OMAR.

The report on OMAR noted that the lack of a clearly defined role for OMAR (except in the development of the consensus conferences) and preoccupation with the administrative details of the meetings have contributed to decreased interest among Advisory Committee members and a high turnover among institute (and division)

representatives. The committee and its subcommittees have been effective, however, in the development of issue papers. Topics covered in the issued papers have included the activities and mandates of NIH, the development of evaluation schema, methods for updating consensus statements, and advice on the definition and reporting of emerging technologies. The committee has also served as a principal means for sharing information about technology transfer issues within NIH (59).

Consensus Development

OMAR'S primary activity has been the administration of the consensus development program at NIH and support of the actual consensus conferences. The consensus development conferences bring together scientists, practitioners, consumers, and others in an effort to reach general agreement on the safety and efficacy of medical technologies. The technologies of interest may be emerging or may be in general use. Recent conferences have tended toward examining emerging technologies, while early conferences generally focused on existing—and sometimes controversial—technologies. The technologies studied may be drugs, devices or medical, surgical, or dental procedures. Since the first conference in September 1977, there have been 32 conferences held and four more are currently scheduled. Table 12 lists the topics, dates, and sponsors.

The first step in planning a consensus development conference is the selection of the technology to be assessed. Since this activity occurs at the individual institute or division level, procedures vary widely. Before a conference topic is finally selected and scheduled at OMAR, it will have been discussed and reviewed for 2 to 15 months at the institute level. It will also have been discussed by the OMAR Advisory Committee to generate suggestions and interest from other institutes that may have escaped the original sponsors. Should the case arise (and it has not to date) that there are more topics identified for conferences than OMAR has the resources to support, the OMAR Advisory Committee would be the body to recommend a priority order in which the conferences would be held.

Once the conference topic has been identified, the planning process begins. OMAR provides the initiative and logistic support and offers guidance based on the experiences with previous consensus development exercises. The planning period typically lasts 9 to 18 months (90). A number of planning meetings, first involving only NIH and OMAR staff, and later involving outside experts, are usually held to delineate the key issues. Also determined during the meetings are the specific questions surrounding the technology under discussion and the approaches to be used in reaching consensus. Individual experts may prepare papers prior to the meeting summarizing the state of the science; alternatively, or in addition, task forces are asked to produce draft documents for consideration at the conferences.

Consensus development panels are carefully constituted to reflect the range of individuals and organizations with expertise and interest in the use of the technologies. They include researchers in relevant fields, members of the pertinent clinical specialties, health care consumers, and others. Without question, however, the panel is overwhelmingly scientific, often reflecting the orientation of its sponsor. The conference is open to the public and audience participation is encouraged.

Most NIH consensus development conferences have used some variation of the following general format. The conference begins with a plenary session, during which individual experts or representatives of task forces present information on the state of the science. Comments by panelists may follow. Also, members of the audience may ask questions or provide comments. In some cases, work groups or task forces then meet to discuss specific aspects of the technology. In a closed session, the panel then convenes in an attempt to reach a consensus on the relevant issues. At the final plenary session, the consensus statement is presented to the audience for comment. At times, the audience comments are incorporated. Panel members who disagree with major conclusions may issue a minority report. A minority report has only been issued once.

Consensus statements are not, and do not attempt to be, regulations on the "proper" practice

Table 12.—NIH Consensus Development Meetings, September 1977 Through November 1982, Office for Medical Applications of Research

Sponsors	Title	Dates held
NCI	Breast Cancer Screening	Sept. 14-16, 1977
NCI	Educational Needs of Physicians and the Public Regarding Asbestos Exposure	May 22, 1978
NIDR	Dental Implants Benefit and Risk	June 13-14, 1978
NCI	Mass Screening for Colo-Rectal Cancer	June 26-28, 1978
NIA	Treatable Brain Diseases in the Elderly	July 10-11, 1978
NINCDS	Indications for Tonsillectomy and Adenoidectomy: Phase I	July 20, 1978
NIAID	Availability of Insect Sting Kits to Non-physicians	Sept. 14, 1978
NCI	Mass Screening for Lung Cancer	Sept. 18-20, 1978
NIGMS	Supportive Therapy in Burn Care	Nov. 10-11, 1978
NIAMDD	Surgical Treatment of Morbid Obesity	Dec. 4-5, 1978
Interagency Committee on New Therapies for Pain and Discomfort (Organizer)	Pain, Discomfort, and Humanitarian Care	Feb. 16, 1979
NICHD	Antenatal Diagnosis	Mar. 5-7, 1979
NHLBI	Transfusion Therapy in Pregnant Sickle Cell Disease Patients	Apr. 23-24, 1979
NHLBI	Improving Clinical and Consumer Use of Blood Pressure Measuring Devices	Apr. 26-27, 1979
NCI	The Treatment of Primary Breast Cancer: Management of Local Disease	June 5, 1979
NCI	Steroid Receptors in Breast Cancer	June 27-29, 1979
NEI	Intraocular Lens Implantation	Sept. 10-11, 1979
NIA	Estrogen Use and Postmenopausal Women	Sept. 13-14, 1979
NIAID	Amantadine: Does It Have a Role in the Prevention and Treatment of Influenza?	Oct. 15-16, 1979
DRS	The Use of Microprocessor-Based "intelligent" Machines in Patient Care	Oct. 17-19, 1979
NIDR	Removal of Third Molars	Nov. 28-30, 1979
NHLBI	Thrombolytic Therapy in Thrombosis	Apr. 10-12, 1980
NINCDS	Febrile Seizures	May 19-21, 1980
NCI	Adjuvant Chemotherapy of Breast Cancer	July 14-16, 1980
NCI, NIA, NICHD, NCHCT	Cervical Cancer Screening: The Pap Smear	July 23-25, 1980
NIAMDD	Endoscopy in Upper GI Bleeding	Aug. 20-22, 1980
NICHD	Childbirth by Cesarean Delivery	Sept. 22-23, 1980
NCI	CEA and Immunodiagnoses	Sept. 29-Oct. 1, 1980
NHLBI, NCHCT	Coronary Bypass Surgery	Dec. 3-5, 1980
NINCDS, NIAID, NIAMDD, NICHD, NIEHS, DRS	Reye's Syndrome Diagnosis and Treatment	Mar. 2-4, 1981
NINCDS, NCI	CT Scanning of the Brain	Nov. 4-6, 1981
NIAID	The Effect of Diet on Hyperactivity	Jan. 13-15, 1982
NIADDK	Hip Joint Replacement	Mar. 1-3, 1982
CC	Critical Care Medicine	Summer 1982
NIAID	Immunotherapy - Treatment of Insect Sting Allergy	Oct. 6-8, 1982
DRS	Validation of Biomaterials	Nov. 1-3, 1982

SOURCE: Office for Medical Applications of Research, National Institutes of Health.

of medicine. Rather they are attempts to represent the best current thinking by a group of scientific experts and others in a position to make judgments on safety and efficacy. Consensus conferences differ from standard state-of-the-art meetings in that consensus panels must consider and seek closure on specific sets of questions, and the format of the conference has been predetermined.

Dissemination

Those conducting consensus development conferences hope that by supplying practitioners with critiques of complex medical technologies, the consensus reports will contribute to an improvement in the quality of medical practice. Dissemination of the consensus statements and supporting materials is thus an essential part of the program. Practicing physicians and others in the health care system, the biomedical research community, and the public are the groups targeted to receive the statements. OMAR assists in the actual dissemination and in the monitoring of the following dissemination activities. Consensus materials and information have been published in the three American medical journals with the largest circulation—the Journal *of the American Medical Association,* the *New England Journal of Medicine,* and the *Annals* of *Internal Medicicine.* Distribution through State medical journals, other scientific publications, mainstream periodicals, and the general press is encouraged, though such distribution is not directly initiated by OMAR (90). A brief review of the literature by OMAR found that most of the consensus reports were published in at least two journals (80). OMAR actually publishes summaries of the conferences in a periodic publication, NIH Consensus Development Conference *Summaries* (81), and distributes it to requesters on its mailing list of over 21,000 names. In addition, the conference reports have been indexed in the National Library of Medicine's Index *Medicus* since the winter of 1980, making their existence even more widely known.

OMAR'S information dissemination activities are focused solely on consensus conferences. These activities are not formally coordinated with NIH's other numerous information dissemination activities, although coordination of information offices is accomplished to a degree through periodic meetings with the Associate Director for Communications. According to the report of the Oversight Committee for OMAR (59), the liaison between the Office of Communications and OMAR is satisfactory. However, work on use of nonpublished media and interpersonal networks discussed by a Task Force on Communications (established in 1975 and abolished in 1978) is not receiving adequate effort. In 1981, a subcommittee on communications of the OMAR Advisory Committee prepared an OMAR dissemination plan. This plan is awaiting implementation.

Other Activities

Since its creation, OMAR has provided a conduit for requests from other agencies for technical advice, generally in the areas of reimbursement and specific technologies. OMAR'S function has been to receive the requests, channel them to the appropriate institutes for action, and return the completed response to the requestin$_{g}$ agency. For reimbursement advice, NIH provides only technical material on the acceptability of a procedure in medical practice; it does not actually develop reimbursement recommendations. These recommendations are currently developed for the Health Care Financing Administration (HCFA) by an office of the Assistant Secretary for Health, DHHS. Formerly, NCHCT developed the recommendations. In 1979 and 1980, NIH answered 63 such requests (59). For specific technologies, OMAR had channeled requests from NCHCT to the various institutes to identify experts to prepare overview papers. This activity does not currently occur, although the mechanism is still in place.

Discussion

In the following ways, OMAR and its activities, particularly the consensus development program, have successfully contributed to appropriate technology transfer. The consensus statements and supporting materials provide a resource to assist members of the health care community and the public in making sound decisions regarding the use of medical and surgical procedures, drugs, and devices. The program has also helped scientists and policy makers to

identify gaps in current knowledge and opportunities for further research (95). And in contrast to some original concern that consensus development would be thought to stifle innovation, there have been reports that the inclusion of recommendations for further research in the statements actually fosters innovation *(95),*

The program has several weaknesses, however. One limitation of the program is in the process itself. For instance, the use of adversary groups and task forces has been almost entirely abandoned recently, and the questions posed have been strictly on issues on which there is enough factual evidence to reach agreement. For the purpose of synthesizing available knowledge, this approach may be adequate (assuming that the available knowledge is all included and understood). Some critics still believe that for the purposes of identifying gaps in knowledge and needs for future research this approach is weak (92). NIH does not agree with this judgment, however, arguing that in instances where consensus cannot be reached, the panels identify areas of needed research. Even when the clearly controversial issues are tackled, critics have voiced concern that the fact that consensus has been reached means that the statements are only bland generalities that represent the lowest common denominator of the debate, and as such are far from the cutting edge of progress (103).

As the office responsible for monitoring the progress and effectiveness of the consensus development program, OMAR has launched two major evaluative efforts. One study will compare alternative strategies for conducting NIH consensus development activities (a look at the process), and another will assess the impact of the conferences.

Apart from questions over the method and process of consensus development, an issue remaining to be resolved is whether the role of OMAR should be expanded, since NCHCT has been disbanded. Although NCHCT'S specific coordination activities are no longer being performed, OMAR is basically functioning the same way today as it did before NCHCT's demise. That is, it utilizes the same intra-NIH procedures for selecting consensus development conference topics, planning the conferences, and disseminating information on them as it did before; and it assists HCFA with technical advice related to reimbursement as it always did. The difference is that reimbursement requests come from a temporary office in the Assistant Secretary for Health's office instead of from NCHCT. The assessments done with OMAR'S assistance focus on safety and efficacy rather than ethical, legal, economic, and political issues. However, OMAR does not have the mandate to conduct such broad-based studies. Additionally, there is no NIH-wide mandate to systematically identify emerging and existing technologies in need of review, as there had been in NCHCT's day. Several institutes do perform this activity —NHLBI's program, though, is certainly the most formalized.

Demonstration and Control Programs

Demonstration and control programs, like consensus development conferences, are formal technology transfer activities. They are undertaken specifically to assure that new technologies that have been shown to be safe and efficacious are applied in clinical practice in the most effective ways. In 1975, the Director of NIH defined the terms as follows:

> Demonstration means either showing that something works, such as patient education, or showing that something that works in an ideaI setting works in a practical field setting. Control has as its goal the reduction of disease, preferably by prevention, and is the ultimate objective of biomedical research. However, its meaning has changed to refer to the extension or diffusion throughout the health care system of an intervention, technology or some other change in the substance of medical practice (114).

Demonstration and control programs are generally discussed together as a category of activities (56,60,114). Technically, they are overlapping activities. Demonstration projects are not always concerned with the control of disease in the prevention sense, although demonstration of the application of any medical technology is intended to affect some aspect of eventual disease reduction. Control programs, however, usually comprise a broad range of activities, of which

the most important are demonstration projects. In a discussion of control programs at NHLBI, a study panel concluded that "well-conceived demonstration projects will conserve limited resources, save money, and reduce the frustration that inevitably results from premature and ill-conceived projects. They will ensure that new programs are well-tested before they are committed to general use" (56).

Demonstration and control programs are not a new NIH activity, but actually started with the National Cancer Institute Act of 1937. In 1946, the Cancer Control Branch was established within NCI to provide grants to State health agencies for cancer control activities. As new categorical institutes were established at NIH, additional disease control activities were added. Some, such as the Heart Disease Control Program, were identified as discrete and visible programs, while others were not separately categorized and funded as control programs per se. In the early 1960's, the control programs of NIH were transferred to the Public Health Service Bureau of State Services. Then, in 1968, the control programs as they existed were phased out, and some components were transferred to the Regional Medical Programs. Demonstration and control activities returned to NIH with the enactment of the National Cancer Act of 1971 and the Heart, Blood Vessel, Lung, and Blood Act of 1972. These activities were expanded to other disease areas with the passage of the National Diabetes MelIitus Research and Education Act of 1974 and the National Arthritis Act of 1974.

The amount of demonstration and control activity varies widely among the institutes. The largest effort, by far, is the Cancer Control Program at NCI; it is the only control program with a line item in the budget, This line started at $5 million in 1973, reached a high of $70 million in 1979, and is set at $55 million for 1982. Corresponding figures for other institutes are not available, but if they were, most would be less than half the NCI amount. The National Research and Demonstration Centers Program of NHLBI is the second largest demonstration and control program at NIH. Programs at NCI and NHLBI are discussed in depth in chapters 6 and 7.

An examination of the statutory authorities for the institutes reveals that demonstration and control are mentioned for only six of the 11 institutes—NCI, NHLBI, NIADDK, NIGMS, NIDR, and the National Institute on Aging (NIA). Of these, only four (NCI, NIADDK, and NIGMS) have specific programs authorized. While there are currently examples of such programs at eight of the institutes, it is clear that the efforts are greater when Congress has specifically mandated the activities,

Some examples of demonstration and control programs are as follows (58):

1. NIAID—accelerated vaccine development.
2. NIADDK—demonstration of prolonged cadaver graft survival with multiple pretransplantation blood transfusions.
3. NCI—numerous activities coordinated by a new Division of Resources, Centers, and Community Activities.
4. NICHD—new methods for managing the diabetic condition early in pregnancy will be tested for effectiveness in reducing the risk of congenital defects among offspring.
5. NIDR—demonstration of fluoride-containing agents under the National Caries Program.
6. NIGMS—development of artificial skin for burn victims.
7. NHLBI—program of National Research and Demonstration Centers.
8. NINCDS—Comprehensive Stroke Centers.

The general orientation of NIH is that demonstration and control programs should involve the establishment of innovative disease control technology through controlled, time-limited projects conducted in limited populations (114). Thus, most of the institutes have some interest in demonstration and control activities.

Information Dissemination

Information dissemination is essential for technology transfer to occur. It is the means by which results travel from one stage in a technology's Iifecycle to another. All information dissemination activities, therefore, affect technology transfer. The activities associated with the more formal technology transfer programs, such

as the consensus development program and demonstration and control programs, are designed to disseminate information about the appropriate clinical use of medical technologies. On the other hand, the dissemination activities associated with programs in the earlier stage in the technology's life (such as R&D or evaluation) are designed to assure that basic knowledge can be translated into solutions potentially applicable to improving health.

Along with its responsibility to develop and evaluate new biomedical knowledge, NIH has had, since its early days, an implicit responsibility to disseminate information about research results to the research community, the health professional community, and the public in an effective and timely manner. However, this responsibility has been made more explicit by Congress over the past decade, reflecting both a feeling that dissemination activities are important and a criticism of NIH's less-than-vigorous efforts in the past (114).

Of the 11 institutes, only four do not have specific mandates to disseminate research results (NIGMS, NEI, NIAID, and NINCDS). The statutory authorities for the seven remaining institutes vary according to the specificity of their dissemination programs. The most specific law concerns NIADDK. It mandates several programs of which information dissemination is a major component, including: the Diabetes Data Group and Clearinghouse, Diabetes Research and Training Centers, arthritis demonstration projects, the Arthritis Data System, multipurpose arthritis centers, and the National Digestive Diseases Education and Information Clearinghouse. NCI and NHLBI also have several designated programs in their statutes, while NIDR, NIA, NICHD, and the National Institute of Environmental Health Sciences (NIEHS) have less specific directives.

Clearly, where Congress has created special provisions for other technology transfer activities, it has also stressed information dissemination. This is evidenced in the original and amended versions of the National Cancer Act of 1971, the National Arthritis Act of 1974, the National Diabetes Mellitus Research and Education Act of 1974. The trend which started with the National Cancer Act has continued and strengthened—the latest amendments to the NIH authority focused on NIADDK, and it is NIADDK that has the most specific dissemination programs.

In 1974, the Director of NIH established a Committee on Dissemination of Research Results to review NIH-wide dissemination activities and develop specific recommendations. This committee produced yearly reports through August 1977, when the fourth and final report was written (53). When OMAR was created, the committee ceased to function. The committee divided the task of information dissemination into programs for three target audiences: research scientists, practicing physicians and other health professionals, and the general public. Although formal yearly progress reports are no longer written, the target groups remain the same.

Dissemination to Scientists

In the area of scientist-to-scientist communication, the primary mechanism is through publication in the more than 2,2oo scholarly and scientific journals. This mechanism, which includes critical review of the results as a condition of publication, safeguards the scientific community against widespread diffusion of incorrect information.

It is generally agreed that this mechanism is effective (114). That NIH ranks fairly high in the scientific literature is evidenced by a recent survey of 1,000 scientist-authors whose published works from 1965 to 1978 were considered the most cited in scientific literature (55). There were 84 NIH intramural scientists among the 1,000, or 10.5 percent of the estimated 800 authors who published in fields relevant to the NIH mission.

The National Library of Medicine (NLM) is NIH's largest activity in the area of scientific information acquisition and storage for easy retrieval. * A major role of NLM is to provide mechanisms for dissemination of information, including 20 online data bases directly accessible

● NLM was the topic of study in an OTA staff paper in 1981 (91) and in a technical memorandum to be completed in April 1982.

at more than 1,530 institutions (91), the Regional Medical Library Program and the National Medical Audiovisual Center. Although there are unresolved issues concerning NLM's future growth and directions, it is regarded as an excellent program.

Dissemination to Health Professionals

In the area of communication of research findings to health professionals, it is not sufficient simply to provide volumes of study results no matter how worthy they may be. A busy practitioner would be inundated by the sheer volume of information if he or she received the full output of published results. For this reason, it is essential that there be a sorting-out process and that communication efforts be concentrated on the portion of research output that is ready for use in clinical settings (114). Thus, NIH conducts a number of activities in addition to NLM activities noted in the previous section. The consensus development conferences and subsequent dissemination of their proceedings, sponsored by OMAR, is the program most directly related to the targeted transfer of technologies. It has already been discussed. In addition, the various institutes sponsor over 100 meetings annually for practicing physicians (53). The Office of Communications, in its annual list of publications (54), targets publications of particular interest to health professionals. And the Lister-Hill National Center for Biomedical Communications (a division of NLM) conducts and supports a continuing research program on the effectiveness and efficiency of biomedical communications.

Dissemination to the Public

In 1977, it was reported that the constituent units of NIH received about 1,500 public inquiries each working day. About 80 percent of those requests came from members of the general public and concerned specific disease problems (54). The volume of requests is even larger today. In response to public as well as congressional pressure, NIH continues to increase its dissemination to the public. The activities are numerous; they include targeting publications in the annual publications list to the general public, supplying audiovisual materials to over *2,000* radio stations and over *700* television stations, preparing instructional films, releasing news briefs, and sponsoring disease-specific public information centers such as the National Digestive Diseases Education and Information Center.

Technology Transfer to Industry

For medical technologies that are physical objects—drugs and devices—the technology transfer process involves industry. It is industry that actually produces and markets the technologies, thereby influencing their application in clinical practice. In many cases, the bulk of the transfer process occurs within the drug and medical device companies, from applied research to technology creation and development, through evaluation, to production and distribution. In these cases, the basic knowledge utilized in the company's applied research is often transferred from an NIH-sponsored program. The transfer mechanism is usually scientist-to-scientist communication through the professional literature or at professional meetings.

In other instances, however, the technology is developed and perhaps evaluated under NIH auspices. It is transferred to industry, then, much later in its lifecycle. Recently, there has been considerable interest within NIH and within Congress on this aspect of technology transfer (58).

Collaborative programs with industry have long been viewed by other agencies as a mechanism to facilitate the transfer process. Indeed, the National Aeronautics and Space Administration recognized early on that involving industry early in the technology development process would increase the likelihood that the technology would be produced. And in the field of technologies for disabled people, the National Institute for Handicapped Research has begun similar relationships with industry.

NIH, with its more recent commitment to knowledge application in addition to knowledge development, is relatively new in its agencywide interest in relationships with industry. For some time, Congress and others have been concerned about the commercial application of useful biomedical research findings. More recently, rela-

tionships with industry are expanding because of budget constraints. There are those, mostly within the government, that hope that the drug and device industries can pick up forthcoming cuts in biomedical research budgets. Pharmaceutical industry representatives, however, have stated that, although they can continue to fund "some areas" of biomedical research, they "can't pick up the massive slack" in available funds (21). Furthermore, relationships with industry are growing due to the clear commercial value in applications from basic science fields where there has been no precedent for profit (e. g., genetic engineering).

Industry patents and licenses are very important aspects of the transfer process. NIH is quite active in this regard, with approximately 370 patents licensed to industry.

The Advisory Committee to the Director of NIH has had as a priority for 1981 the relationship between NIH and industry. This priority continues today. Issues of concern include the following:

- how patent rights are allocated;
- how patent royalties are allocated—among scientists and their university, among universities and industry-and whether the government can recoup some of its investment in research;
- whether a longer period of patent protection and licensing is needed;
- how and when the government should invoke its march-in rights, the right to revoke a university's patent license if the license is not properly handled;
- what the best model for patent administration at universities is; and,
- what the impacts of patenting on the now-open system of communications in biomedical sciences will be.

Training

Since the objective of training programs at NIH is to produce more and better biomedical researchers, these activities do not have a direct impact on the technology transfer process. In several ways, however, they do affect the process indirectly. First, training funds develop the personnel resources to develop and evaluate technologies. This effect is most important to targeted technology transfer when the researchers are trained in conducting evaluative studies to prevent the premature diffusion of untested technologies into clinical practice.

Second, when training is conducted at the specialized centers funded by NIH, such as the Diabetes Research and Training Centers, there is **a** formal combination of the training and technology transfer functions. The combination assists in current transfer and orients the trainees to develop similar programs of their own in the future. Finally, since much of the training occurs in institutions associated with clinical practice, interaction between the researcher trainees and the health professionals can allow for informal technology transfer.

Table 13 shows training grant appropriations by funding component from 1950 to 1980. From 1950 to 1967, the increases in funds were large, and the next period, until 1976, was one of fluctuation. Regulations issued under the National Research Service Award Act of 1974 in 1975 directed that awards could be made only in fields determined to be in need of research personnel; these regulations were partially responsible for the drop in 1976. Since that time, increases have been steady, particularly for the larger institutes. Thus, the problem of instability cited in 1976 by a congressional investigation of NIH (114) and the President's Biomedical Research Panel (97) was somewhat alleviated. Recent budget cuts are likely to affect stability.

Table 13.—Training Grant Appropriations by Funding Component, Fiscal Years 1950-80 (amounts in thousands of dollars)

Fiscal Year	GRS-NIH	NCI	NIMH	NHLBI	NIDR	NIAMDD	NIAID	NINCDS	NICHD	NIGMS	NIEHS	NIA[5]	NEI[5]	~_3	Total
1950		2,625	*2,956*	834											6,415
1951		2,415	*3,349*	888											6,652
1952	86	2,415	*4,000*	891	.“.”										7,392
1953	86	2,725	*3,750*	1,623											6,184
1954		2,855	*4,176*	3,028		250		504			“.				10,813
1955		2,725	4,310	2,762		250		1,004							11,051
1956		2,725	5,885	3,142		950		1,600							14,502
1957	500	4,675	12,000	4,400	500	1,850		4,150	...”		“‘	:	:	:“	28,075
1958	500	4,725	14,000	5,135	500	2,450	650	4,972							32,932
1959	6,040	6,050	18,213	7,152	450	4,435	1,787	5,775	“.”		“‘				49,902
1960	13,040	7.205	26,208	8,679	1,100	6,298	3,621	8,888	“‘“	.	.	.	.	.“‘ .“	75,037
1961	27,000	7,055	39,470	11,970	2,985	8,300	4,790	8,450							110,000
1962	31,000	9,055	34,858	13,104	4,791	10,300	5,400	10,OOO	: .....: ””. ‘:.						118,506
1963	35,442	13,470	49,373	16,000	5,853	13,034	7,200	13,767	. . .			.....:...	.“-”	::””	154,139
1964	35,682	12,482	65,188	14,801	4,759	13,220	7,988	14,382	t 4,142						172,602
1965	37,182	9,000	73,213	14,984	4,708	13,690	8.239	14,751	5,544					.: “‘ .	181,311
1966		10,900	86,231	17,228	5,203	14,208	9,059	17,757	7,937	41,375					209,898
1967	250	11,068	94,448	~7.525	5,248	14,857	9,103	18,633	9,619	43.735					224,486
1968	318	11,350	(‘)	17,698	5,469	15,706	9,251	18,780	9,762	45,729	4,745	.			138,806
1969	326	11,641		16,150	5,609	16,109	9,468	19,262	10,012	46,901	3,892 .:::::” :.. ...::::”. :..... . .....:::::				141,390
1970	352	11,941		19,008	5,495	17,454	8.972	17,950	9,892	48,477	3,617	3,313			148,469
1971	(3)	10,774		17,643	5,208	15,072	8,972	14,300	10,142	43,746	3,117	2,998	352		132,322
1972		[4]16,474		18,701	5,582	15,976	9,457	15,158	10,751	46,371	3,304	3,178	373		145,325
1973[6]		16,750		19,343	5,270	15,072	6,982	16,324	11,598	47,511	4,131	3,398	416		148,795
1974[7]		13,742		16,089	5,515	12,312	7,933	16,516	6,552	39,247	2,900 .....::.	3,056	391		126,253
1975		17,097	. . .	14,515	3,692	10,078	5,351	10,310	6.680	44,940	2,915	1,156	3,194	388	120,274
1976		12,888		11,839	3.235	1,247	4,537	4,006	6,644	37,599	1,453	1,133	3,194	160	87,915
1977		15,541		17,733	3,309	7,234	5,766	2,450	5,877	40,988	3,108	1,629	2,387	411	108,551
1978		15,191		19,321	3,219	12,587	5,556	3,059	6,097	41,580	4,036	1,856	1,990	412	114,904
1979[9]		17,110		19,098	2,780	12,863	5,875	3,584	8,370	42,371	4,293	1,854	3,452	469	121,919
1980[10]		22,901		27,622	3,487	18,123	7,097	3,854	8,342	42.092	6,121	2,170	3,530	597	145,936

[1] Derived by transfers from other NIH appropriations as authorized by Congress

[2] Transferred 10 HSMHA July 1, 1967

[3] GR & S discontinued Research Resources *appropriation established*

[4] Includes portions of $100,000,000 Cancer Conquest Program and $40,000,000 supplemental

[5] Formerly a part of the Neurology Institute

[6] No *appropriation bill signed in 1973 Figures* are baaed on the continuing resolution

[7] Reserve legislated by P L 93-192 not reflected

[8] Formerly a part of NICHD

[9] Authorized by P L 95-482 (Continuing Resolution)

[10] No enacted appropriations, authorized under continuing resolution

SOURCE National Institutes of Health