

Section Three

Purpose and Need

3.1 PURPOSE

The mission of NIH, as delineated in the original and amended federal legislation directing the agency's activities, is to conduct biomedical research, educate and train researchers, assist in the transfer of technology, and disseminate information in the biomedical and associated sciences on behalf of the health and welfare of American citizens. The purpose of the Master Plan is to provide guidance for realistic, orderly, and comprehensive physical development of the Bethesda campus so that NIH can continue to perform its mission. Many of the campus research and clinical facilities have aged beyond their expected useful life. The Master Plan is a keystone planning element in the modernization of these physical facilities. Improvements to the physical plant, in turn, will lead to an enhancement of the missions carried out by NIH at the Bethesda campus.

The Master Plan 2003 Update is a revision of the 1995 Bethesda Campus Master Plan, and is identified as the "Master Plan". It accounts for physical and other changes within and without the campus that have occurred in the interim. The Master Plan outlines a coordinated long term land use strategy for the campus. It establishes a conceptual integrated framework for physical development that permits NIH to organize the arrangement of potential future buildings, necessary supporting infrastructure such as roads and utilities, access, and open areas cohesively. Potential development sites and natural areas to be protected are identified. General conditions, criteria, and constraints are delineated. An approximate sequence of steps for implementation of the plans and reaching the development objectives is outlined. It is also the intent of the Master Plan to encourage active dialogue among NIH management, the NIH scientific and support community, and the general public and citizens by fostering a better understanding of the ramifications of proposed policies and plans.

NIH administrators, planners, architects and engineers, when implementing individual projects, will use information and recommendations in the Master Plan. Local jurisdictions and utilities can use this same source to anticipate and plan for the effects that NIH proposals may potentially have on their infrastructure and systems.

It is important to note that a master plan is a document of broad and general scope. It must be flexible, and is not a fixed blueprint. Variances within the constraints established in the Master Plan are expected to occur. Small projects needed for immediate ad hoc operations, routine maintenance and repair projects, and other projects that produce no significant permanent impact, are not necessarily delineated. Personnel and space estimates covering the next five years, including projects now under design or construction are established with some degree of confidence. As the planning period is extended to 10 years and beyond, projections become increasingly speculative and contingent.

All the growth and projects depicted in the Master Plan may not occur. On the other hand, NIH must respond to future Congressional and Presidential decisions regarding its mandated mission. These policy decisions, in turn, reflect demands and pressures applied by the American people. Changes in the national health policy can be expected over the next decade, and within its mission, directives to NIH could change as a result. While one strong point of NIH is the ability to react to new directives and mandates using existing facilities and personnel, many conditions, such as new fields of research, could lead to changes in growth forecasts at NIH over the next 20 years from those proposed in the 2003 Draft Master Plan Update.

Although the Master Plan covers a planning horizon or period of 20 years, it is the intent of NIH to review the Bethesda campus Master Plan at approximately five year intervals. The incremental effect of campus growth during the five year interval would be assessed, if this should occur, and evaluated with

community input and participation. The five year Master Plan reevaluations and updates would be critical in this process.

3.2 NEED FOR MASTER PLAN

Intramural research is research conducted by NIH scientists, doctors, and visiting researchers and post-doctorate trainees at NIH facilities. NIH researchers and staff also administer, monitor, and review biomedical research programs completed by private and non-federal institutions under NIH-funded contract or grant programs. The latter is defined as extramural research. Personnel in NIH office buildings outside the campus around Montgomery County are primarily involved in administration and management of extramural programs. NIH also has mandated missions to train and educate biomedical researchers and provide an exchange of biomedical research information.

The intramural research program possesses several unique characteristics that set it apart from the extramural program. Funding for this research is long term and relatively stable, the Clinical Center patient investigative facilities are readily available, and there are few, if any, administrative and management distractions for scientists engaged in research. It must be emphasized that a strong extramural research program requires a vigorous and high quality intramural research program. The quality of the intramural program, in turn, is dependent on the ability of NIH to recruit, attract, and retain highly qualified senior scientists and promising young investigators. Since NIH must compete with universities, research institutes, hospitals, and the private biomedical research sector for scientific personnel, its ability to recruit is influenced by the quality of its physical facilities and character of the campus in comparison to other research facilities.

To accomplish its purpose and mission, NIH is organized into Institutes and Centers (ICs). Through the Clinical Center, these ICs are closely interwoven into an integrated organization and network that can function efficiently only if nearly all elements of the organization are present on campus. While each Institute or Center nominally concentrates on and is responsible for specific areas of biomedical research and training, working relationships as complex as those between organs in the human body exist between them. Other organizational components provide essential and specialized services to all of the Institutes and Centers under centralized control.

In dozens of interviews conducted to determine future research personnel and space requirements, directors of the ICs repeatedly expressed the need for maintaining a "critical mass" of facilities, personnel, talent, and support on the campus that is essential for the conduct of the U.S. biomedical research program, not only at NIH, but also throughout the U.S.

Studies conducted by NIH along with 2,000 representatives of the scientific community indicate that basic and clinical research will become even more integrated and related in the near future. A clear understanding of the need for facilities and personnel can only be gained, albeit superficially, by a deeper look at the functioning of the NIH organization at Bethesda and its functional relationships.

3.2.1 Clinical Center - Research Relationships

The heart of the NIH Bethesda campus is the Warren Magnuson Clinical Center, about which research activity revolves. The Clinical Center is located in the Building 10 complex that encompasses more than 2.3 million square feet of occupiable floor space. The center is the focal point where biomedical science and research at the laboratory bench is rapidly transformed into practical treatments and accepted medical practice through direct interface with human patients. Most of the functions of the Magnuson Clinical

Center will be transferred to the new state of the art Mark Hatfield Clinical Research Center when the latter opens in 2004. Hospital spaces in the Magnuson Center will then be converted to clinical research.

A clinical center is a place where clinical trials are conducted. Classically, clinical trials are tests or protocols where one group of patients is given a medical or surgical trial treatment or procedure, while a second group is given nothing (placebo) or an alternative procedure. The efficacy of the two treatments or procedures is compared. NIH uses its Clinical Center in many ways other than the classical one to advance biomedical research.

The NIH Clinical Center hospital has many of the facilities found in a general hospital, but unlike most hospitals, the Clinical Center does not offer diagnostic or treatment services to the general public. Yet, some 6,500 employees including 1,200 full time physicians and 600 registered nurses work in the complex. About 4,000 of the Clinical Center staff are engaged in research while about 2,000 support the hospital program. All clinical services are free of charge. All patients in clinical trials are volunteers.

Patient admission is selective. They are chosen by Institute physician researchers based on a number of factors. Some are selected on information supplied by referring doctors who may be the patient's family physician. Others have a medical condition under study. They can include the chronically and terminally ill, those with rare diseases, disorders, and conditions, and those willing to undergo new procedures with greater uncertainty in the risks involved. Patients are recruited nationally, and in cases of some rare diseases, internationally. Over 6,500 people are admitted for study and treatment annually as inpatients. Many inpatients remain for weeks or months, although the average stay is only 7.4 days. Outpatients may live at home and report daily, weekly, monthly or at some other interval. Approximately 74,000 outpatients visit the Clinical Center annually.

Patients also include healthy individuals. Five hundred healthy people are admitted annually as normal volunteers representative of the American population in general, and over 11,000 healthy subjects have been tested at the Clinical Center. They provide vital information on the physical and mental characteristics of good health, early signs of disease or dysfunction, and the effects of aging over a long period.

Upon admittance, patients are assigned to the care of a "clinical associate", a full time physician, who will be responsible for the patient and for conducting the research studies for which the patient is admitted. Extensive oral and written interviews, examinations, and testing are performed on the patient. Collected information, along with that generated during the study, is entered into a computerized data bank in the Center.

Information about the patient's medical condition and status is passed through computer printout to other researchers on the campus. If the patient is willing to participate voluntarily, he or she may be introduced to further experimental clinical procedures or testing for vital information under the auspices of a second or third clinical associate. These further procedures may be done simultaneously or sequentially with the primary studies depending on the protocol worked out among the clinical associates. Patients may have to endure procedures well beyond that encountered in a general hospital. They may be connected to monitoring or measuring equipment or have repeated tests or samples taken for weeks at a time. They may ingest radioactive isotopes to trace substances passing through and around the body. Genetic material may be extracted. The experimental procedure may have unforeseen side effects.

The Clinical Center at NIH is the largest and most advanced center in the world devoted exclusively to research. About half of all the dedicated federally funded clinical research patient beds in the U.S. are at the Clinical Center. About 50% of all U.S. clinical research is done at NIH Bethesda.

Each floor of the Clinical Center Complex hospital has patient wards and biomedical research laboratories. Laboratories may be directly across the hallway or adjacent to patient rooms. There are about 1,600 individual laboratory and research spaces, and 270 patient beds in the complex. In response to a review of Clinical Center operations, several institutes indicated that bed-laboratory adjacency was of considerable value in facilitating transitional basic and clinical research. It is estimated that about 49 percent of the laboratory facilities are on the same floor as complementary clinical facilities. The ICs further indicated that it is desirable to have an additional 38 percent of their clinical and laboratory facilities in the same building, if they could not be placed necessarily on the same floor.

Research scientists and clinical physicians work side by side directly with patients. Observations at the bench in the laboratory quickly yield ideas for clinical application. Clinical observation at the bedside can be tested at once, quickly stimulating new areas for scientific inquiry. It is estimated that clinical trial results at NIH are obtained in about half the time it takes at standard hospitals and extramural facilities.

Clinical programs involve extensive collaborations among research groups. During 2002, over 900 protocols involving 81,900 inpatient and outpatient visits were active in the Clinical Center. Of these protocols, 50 percent were therapeutic, 35 percent concerned pathogenesis or natural disease history, and the remainder evaluated new diagnostic procedures. Some clinical trials were in their fourth phase of study.

3.2.2 Institute-Clinical Center Research Relationships

The NIH Bethesda campus has the largest concentration of biomedical scientists and clinical researchers in the world. Over 4,000 campus personnel have Ph.D. or M.D. degrees, or both. All biomedical academic disciplines are covered in this one location. World renowned experts who are aware of the latest advances on the fringes of science, medicine, and research protocols are present. Specialists are available in new investigative areas.

Similarly, the wide variety of resources available in laboratory spaces, equipment, chemicals, biological agents, and other support facilities accelerates research at NIH. Costly equipment can be shared or borrowed. Elaborate equipment can be operated by specialists. In a few cases, NIH is the only location with a specific resource. Handling and management of research and Clinical Center Complex wastes are centralized.

The Institute research laboratories and facilities outside Building 10 are operationally tied to the laboratories and facilities in the Clinical Center Complex. Research completed elsewhere on the campus is frequently related to that undertaken in the Clinical Center. It may be clinical research not requiring daily contact with patients. Individual scientists and clinical physicians may transfer back and forth between laboratories in other buildings and the Clinical Center as experimental conditions dictate. Outlying laboratories not only have access to the Clinical Center patient computer data bank, but also have access to tissues, genes, bacteria, viruses, and other materials extracted from patients for use in laboratory experiments.

Modern biomedical research has become increasingly complex and interdisciplinary. Work is progressing from microscopic to the molecular, from the study of bacteria and viruses to genes. At this level, differences between disciplines of study, and between pure scientific research in the laboratories and clinical research, become blurred. While individual institutes have the strongest ties to their own programs, there are also complex administrative and research relationships among the ICs. Intramural collaborative efforts are increasing and are expected to continue to do so with increased emphasis in genetic research and therapies.

The accomplishments of scientists in the NIH intramural research program are numerous, and cover a broad spectrum of inquiry. Intramural scientists have made important contributions to the advancement of biomedical science that have benefited the health and quality of life of the general public. Examples include solving the genetic code; elucidating the metabolism of adrenalin hormones and drugs in the body; unraveling the mechanism for protein folding; discovering slow viruses and their causative role in diseases; developing the blood test for AIDS; and uncovering the role of viruses in tumor development.

Research in any one of a number of parallel programs among the Institutes may trigger an insight leading to cure or control of the affliction. Researchers attend formal and informal seminars and conferences on the campus which reveal final results or results in progress. Conferences reveal the results of extramural research as well as that done on campus. Researchers also maintain informal contact. They are helped significantly by the quick exchange of information between groups that subsequently has synergistic effects on the overall effort. Based on the information transferred, some experiments may be stopped, others shifted in direction, and promising new ones started.

Over the last decade, the trend in collaboration among the Institutes has increased significantly. Researchers from a number of Institutes share facilities in Building 40, the Vaccine Research Center, which opened in 1999. Researchers from ten individual NIH Institutes will occupy the Neuroscience Research Center, now under construction, to conduct unified biomedical research involving the head, brain, and neurological systems.

The NIH intramural research program is also unique in that it is not subject to grant programs and income pressures as are private sector biomedical facilities. Requirements in most academic institutions lead most investigators outside NIH to select research topics that will yield prompt results. Since research grants are renewed competitively every few years, no results mean no renewal. Elimination of these pressures permits the NIH intramural research program to undertake several types of studies including interdisciplinary studies between Institutes which are essential, but not possible in the private arena. These include:

1. Long term biomedical studies
2. Quick response investigations
3. Low potential yield investigations
4. Verification - refutation studies
5. Disinterested advice and opinions

- ***Long-Term Studies***

NIH undertakes clinical and laboratory studies which may take years or decades to yield fruitful results. For example, one study by the National Institute on Aging (NIA) involves the recurrent and thorough examination of a large cohort of nominally healthy patients to study the physiological, biochemical, and psychological status of the individuals as they grow older. Already the study has demonstrated that many conditions previously accepted as part of the aging process, such as memory loss and excessive fatigue, are caused by treatable diseases or disorders, not by aging per se. While work is completed under the auspices of NIA, nearly all of the other campus Institutes are involved where findings are within their disciplines. Another long-term research arena is work on slow viruses where diseases become evident only after years of latency.

- ***Quick Response Investigations***

At NIH, intramural researchers need only the approval of Institute directors to proceed with new investigations. They can respond quickly to new research opportunities and public health concerns and

emergencies. Intermediate results in work can indicate an entirely new direction for the work. Results from other research on the campus can be immediately tied to ongoing research, again rapidly changing the course of work.

For example, an NIH investigative team was working on the human leukemia virus. When the concerns about an AIDS epidemic exploded on the American consciousness, they suspected a related retrovirus. Within days, they switched to searching for the virus.

- ***Low Potential Yield Investigations***

Without the pressure for immediate results, NIH researchers are free to pursue investigations with a comparatively low potential yield for immediate results. Younger investigators, in particular, benefit. They are permitted to pursue research off the beaten path, or research that is not glamorous or popular. NIH also permits them to investigate new ideas and new theories. Those studies materially contribute to the broad base of the pyramid of biomedical research. These programs have resulted in numerous Nobel Prize winning discoveries and investigations including Nirenberg's unraveling of the genetic code, and Gajdusek's discovery of an entirely new class of slow viruses that cause serious neurological diseases. Nirenberg had never worked in the field of protein synthesis and would in all likelihood not have qualified for a grant.

- ***Verification - Refutation Studies***

Intellectual excitement and honor associated with discovering the causes of diseases and disorders or their cures is far greater than proving or disproving the findings of others. Publication of findings about the causes or potential cures of diseases in scientific journals does not necessarily mean that the research methods or conclusions are accepted as correct. A critical contribution of the intramural research program is verification - refutation research of claims made by others, particularly with respect to clinical trials. Trials can be arduous, time consuming, and expensive. Few other institutions have the fiscal means and the collective expertise of the NIH Bethesda research staff to support refutational research. These studies frequently involve two or more Institutes working in the Clinical Center.

- ***Disinterested Advice and Opinions***

Intramural NIH scientists are the major U.S. source of disinterested advice on biomedical research with an unparalleled public credibility. Intramural scientists and physicians make important contributions to NIH Consensus Development Conferences, which are open to the public. These conferences have become preeminent forums for resolution of scientific arguments about what is or is not effective in current medical practice. The public relies on NIH to give disinterested advice and opinions about research in the private sector.

3.2.3 Administrative-Institute-Center Functional Relationships

The Bethesda campus is the administrative center and headquarters for NIH research activities. The Office of the Director is located here. All Institutes and Centers (IC) have a respective IC Office of the Director that provides immediate access to the NIH Director.

The directorate offices are responsible for the overall scientific direction and administration of NIH. At the directorate level, decisions reflecting development of coordinated strategies within annual budgets must be made. Individual Institute directorates define program initiatives and funding decisions. NIH, however, is involved in hard science at the laboratory bench. Its administrative procedures must conform to those of the scientific establishment in general. Two administrative procedures used in general science

greatly influence those at NIH. They are the method of funding both intramural and extramural research and the scientific peer review of research.

These procedural requirements inextricably intertwine the administration of individual Institutes with one another, and tie administration to the scientific or technical staff. In dozens of interviews, IC directors emphasized the importance of their close proximity to one another in running their extramural programs.

When mandates or requirements for biomedical research first reach NIH, the routes taken to find solutions are not necessarily self-evident. Institute directors along with laboratory and research directors and other appropriate scientific personnel make decisions on whether to complete work intramurally or extramurally. If intramurally, decisions are made on which Institutes will do which work. Several research programs or initiatives may be begun in parallel.

When an extramural research need is identified at NIH, and private outside researchers or facilities are used, the work is handled by grant, contract, or agreement. This research activity may be routine, may not require Clinical Center facilities, may be large volume work, or work done by outside specialists.

NIH is different from most other federal agencies, however, in using grants, contracts and cooperative agreements to fund the extramural research program. Each year NIH receives thousands of requests for extramural biomedical research grants from universities, research hospitals and research centers. In Fiscal Year 2000, NIH made over 35,000 grant awards for biomedical research and training. In contrast to other federal government agencies which receive specific proposals to complete specific work requested by the agency, grant applications often cover any potential research that the applicant feels worthy of study. Proposals may be related to ongoing research at NIH, may be directed to independent research by outside specialists, or may even be serendipitous, pursuing an idea uncovered in the course of ongoing research.

The Office of Extramural Research (OER) is the gateway for all extramural research and training programs. It operates several computer-based data systems for managing, tracking, and evaluating research. Since 1946, NIH has employed a two-tier peer review system to ensure that the best science is funded. The first level of peer review is performed three times each year by more than 150 Initial Review Groups (IRG) that assess applications for scientific and technical merit. The IRG members include respected and knowledgeable extramural scientists. Their assessments of the grant requests are compiled by OER in a summary statement that critiques the proposed work and gives it a priority score and percentile ranking. In all, about 2,400 individual reviewers participate in the program.

Once the technical applications are reviewed by the IRG, national advisory councils serving the Institutes and Centers (a second review tier) review the applications for program relevance and make recommendations to the Institute and Center Directors. The administrative directorate, in consultation with NIH extramural program staff, makes funding decisions that maximize scientific value for given budget allocations. Discussions occur between Institutes to avoid duplication of work and to coordinate extramural programs, both with intramural studies and among the different Institute extramural programs.

On the average, only about 20% of all research fund requests are funded. Yet, consistently, about 85% of all NIH research expenditures are allocated to the extramural contract and grant research programs.

3.2.4 Training of Biomedical Researchers

It is no coincidence that much of the top award winning and most cited science is done in a few dozen institutions around the world. There is a triad of relationships between facilities, personnel, and the

research performed. High quality facilities that permit research at the cutting edge of scientific investigation attract world class talent. At some point, there is sufficient talent and quality of research to draw other first class scientists into the organization. This is a high priority for NIH.

The critical mass of tenured senior scientists and clinical physicians, along with the largest combination of clinical facilities and laboratories in the world, make the NIH Bethesda campus unparalleled as an education center and training ground for young researchers. About half of all researchers on the campus are post doctorate fellows paid by NIH, or Special Volunteers and Guest Researchers.

Most of these researchers work at NIH for two or three years and then deploy to universities and medical research centers worldwide. NIH is the primary training center for third world researchers who will be leaders in developing their countries' national health programs. The intramural research program has trained more than 50,000 M.D.'s and Ph.D.'s, particularly M.D.'s who are clinical physicians bridging the gap between science and bedside care. Of all M.D.'s trained in the program between 1975 and 1985, 90% remain in research and teaching. In large part, the U.S. biotechnology industry has been spawned by program graduates. NIH alumni have cloned NIH intramural programs throughout the academic and industrial world.

The quality of the training at NIH is exemplary. As of 1995, five NIH staff scientists had received the Nobel Prize and 14 Nobel Laureates worked at one time or another in the intramural program. More significantly, 98 other researchers had earned the Nobel Prize in physics, chemistry, and medicine for work associated with the NIH extramural program. A total of 109 members of the National Academy of Sciences have worked in the intramural program. NIH intramural program scientists have won 34 Lasker Awards. In a 1991 analysis of scientific productivity, NIH ranked near the top not only in quantity, as measured by the number of papers accepted for publication, but also in quality, as measured by the number of citations per paper by other researchers, particularly in the categories of AIDS, gene therapy, and cardiovascular and respiratory medicine research. More than 10% of the world's most frequently cited biomedical research scientists, including four of the top 10, work at NIH. Although NIH intramural researchers receive only 5% of the nation's biomedical research budget, they are responsible for 26% of the most influential research based on frequency of citation of work by others.

Maintenance of research staff and top quality facilities is essential if the U.S. is to retain its competitive edge in biomedical research, which in turn is due in part to the existing intramural program. The number of research physicians is declining nationwide. This is due to economics; medical school tuition is prohibitive. Young physicians are driven to practice to pay off enormous education debts. Even if interested in research or teaching, they frequently cannot risk further indebtedness. Moreover, many private research institutions may be unwilling to, or cannot afford to, take a chance on hiring young physicians potentially rich in talent, but limited in clinical or laboratory experience. The NIH intramural program offers an opportunity to overcome these difficulties.

3.2.5 Essential and Specialized Support

A complex web of organizations that provide essential support services to the Clinical Center and Institutes is also on campus. Full exposition of the intricate administrative and functional relationships between all support organizations and the Clinical Center and Institutes is beyond the scope of this EIS. The following is a partial listing or extract of the many support functions provided on campus.

- Training of researchers in laboratory safety.
- Training of employees in fire protection and evacuation.
- Police and fire protection.

- Emergency response to incidents with special expertise in biomedical research and hospital conditions.
- Planning, engineering, architectural, and construction services for new facilities and those undergoing alteration.
- Renovation and modification of research and hospital spaces. On the average, over 500 hundred such projects are underway at any given time.
- Supply of over 6,300 laboratory and hospital items such as equipment; furnishings; chemicals, biological, and radioactive materials, and consumable materials.
- Design and fabrication of research and hospital equipment in electronics, machine, carpentry, plastics, and glass shop that are not available as off the shelf items.
- Maintenance of repositories of viruses, bacteria, molds, yeasts, fungi, and healthy and diseased tissue for study and replication of experiments.
- Maintenance and care of animals used in research.
- Supply of steam and chilled water for heating and cooling buildings and use at the laboratory bench.
- Maintenance and operation of campus utilities such as water, electric power, communications, natural gas, and sanitary waste.
- Management and inspection of facilities for compliance to applicable laws, regulations, and NIH Bethesda site permits.
- Management, marshalling, treatment, and disposal of general, chemical, radioactive, and hazardous waste.

– † † † –

