

**Memorandum**

Date FEB 5 1996

From June Gibbs Brown
Inspector General *June G Brown*

Subject Audit of the National Institutes of Health's Use of Heart Surgery Contracts with Private Hospitals (A-15-94-00022)

To Harold E. Varmus, M.D.
Director
National Institutes of Health

The attached final audit report addresses the National Institutes of Health's (NIH) use of contracts to obtain routine cardiac surgery. The objective of our audit was to determine how the NIH's National Heart, Lung, and Blood Institute (Heart Institute) used surgery contracts in support of its research mission.

The Heart Institute closed its Surgery Branch in January 1990. In the 4½ year period which followed, the Heart Institute contracted with four Washington area hospitals to provide surgeries to 346 patients at a cost of about \$9 million.

About \$5.1 million of this amount was spent on surgery for 221 patients as an incentive to have them volunteer for research protocols (approved plans of research) primarily investigating coronary artery disease. The Heart Institute officials justified this policy as the only effective way to attract patients with coronary artery disease to research. However the Heart Institute:

- o Did not have a written recruitment policy and had not explored alternative methods of recruiting patients.
- o Provided free surgery to patients who were not on a research protocol at the time they received surgery. (11 of 45 patients whose medical records we reviewed were not on research protocols.) These patients had not signed a research protocol consent form.
- o Provided free surgery to foreign nationals without having a policy regarding their inclusion in research. (24 of the 221 patients were foreign nationals.)

The remaining \$3.9 million was spent on providing surgery to 125 former Surgical Branch patients (15 of the 125 were foreign nationals) who were not participating in current research protocols. These former Surgical Branch patients had at one time received heart valve surgery at NIH and were now having the heart valves replaced, or were receiving bypasses and angioplasties. The Heart Institute officials told us they did not intend to continue to care for former valve patients after the closure of the Surgical Branch because it

was no longer doing research on valves and such patients usually cannot qualify for coronary artery disease protocols. However, according to the Heart Institute's Director, he decided to continue treating these patients after receiving requests from several congressmen that the Heart Institute consider the continued treatment of former patients even though not related to any research being conducted by the Heart Institute.

Since the start of our review, the Heart Institute has taken some steps to improve its use of contract surgeries. For instance, the Heart Institute reinstated a requirement that private insurance pay their share of the cost of the surgery, with the Heart Institute paying only the deductibles and coinsurance costs of the insured patients. The Heart Institute also developed an official policy on the inclusion of foreign nationals in research.

We are recommending that the NIH:

- o in coordination with REGO II activities, conduct a formal study of the Heart Institute's recruitment practices and eliminate the provision of routine surgery to patients not on research protocols including former Surgical Branch patients;
- o develop a formal patient recruitment strategy based on the results of the study;
- o re-emphasize to Heart Institute staff the necessity of adhering to all requirements relative to research protocols in every case involving a patient undergoing research prior to surgery; and
- o ensure that the Heart Institute's recently developed policy regarding the inclusion of foreign nationals in research is complied with by all staff.

In responding to our draft report, NIH generally agreed with all but one of our recommendations. It stated that it wants to continue to see (as outpatients) former Surgical Branch patients who suffer from congenital and valvular heart disease. According to the NIH, while no research is conducted on such patients, the clinical training opportunity provided by seeing such patients helps NIH recruit young cardiologists and retain senior staff cardiologists. The NIH stated it also believes it has an obligation to admit and provide surgery to such patients who may be at high risk if discharged without surgery. As a general comment in its response, the NIH noted that readers should be aware that the Heart Institute's decision to obtain cardiac surgery through contracts resulted in significant savings and scientific benefits. It also noted that it is important to evaluate the potential impact of the report's major recommendations on the ability of the Heart Institute to sustain a clinical cardiology research program.

Page 3 - Harold E. Varmus, M.D.

The NIH's comments and OIG's response are discussed in more detail on page 12 of the attached report. The NIH's comments are included in their entirety in the Appendix of this report.

We would appreciate being advised within 60 days of the status of corrective actions taken or planned on each recommendation. Should you wish to discuss this report, please call me or have a member of your staff contact Joseph J. Green, Assistant Inspector General for Public Health Service Audits, at (301) 443-3582.

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**AUDIT OF THE NATIONAL INSTITUTES
OF HEALTH'S USE OF HEART SURGERY
CONTRACTS WITH PRIVATE HOSPITALS**



**JUNE GIBBS BROWN
Inspector General**

**FEBRUARY 1996
A-15-94-00022**

EXECUTIVE SUMMARY

This final report provides you with the results of our audit of the National Institutes of Health's (NIH) National Heart, Lung, and Blood Institute's (Heart Institute) use of routine cardiac surgery to support its needs. The surgeries are provided under contracts with four Washington, D.C. area hospitals.

BACKGROUND

The Heart Institute, one of NIH's 15 categorical disease institutes, provides leadership for a national research program to prevent, diagnose, treat, and cure heart, blood vessel, lung, and blood diseases. To achieve these goals, the Heart Institute supports a program of basic research and clinical investigations at the NIH Clinical Center (a research hospital located at NIH in Bethesda, Maryland).

Patients are normally referred to NIH by their personal physician. Shortly after being admitted to the Clinical Center, patients undergo a series of standard diagnostic procedures. These procedures include: cardiac catheterization, echo cardiograms, and magnetic resonance imaging. The procedures help determine if the patients qualify for research protocols (written plans of research) and could also represent a necessary component in the research protocol. After participating in research, patients may receive heart surgery for their medical conditions.

Heart surgery used to be provided free at the Clinical Center. However, in January 1990, the Heart Institute closed its Surgical Branch and discontinued providing heart surgery at the Clinical Center. According to Heart Institute officials, the Branch was closed because the surgery it conducted was no longer considered to be important research and it was no longer feasible to maintain a staff of highly qualified heart surgeons given the restrictions of Federal salary levels. Also, the Heart Institute found that necessary surgical support could be obtained at substantially less cost (about \$2 million per year) at local hospitals. The Heart Institute told us it cost about \$10 million a year to provide heart surgery at the Clinical Center. Because of these and other considerations, the Heart Institute decided to contract with four Washington area hospitals for surgery to support the work of the Heart Institute's Cardiology Branch.

During the 4½ year period January 1990 through July 1994, the four contract hospitals performed 427 surgical procedures on 346 NIH patients at a net cost¹ of about \$9 million. The surgical procedures, which were provided to treat patients preexisting medical conditions, included: 117 coronary artery bypass grafts (bypasses); 97 percutaneous transluminal coronary angioplasties (angioplasties); 105 artificial heart valve replacements; and 108 surgeries to repair other congenital heart defects (including valves) and to correct problems related to other heart disease. The cost for these procedures differed based on patients' medical conditions and type of procedure. We noted that costs usually ranged between: \$30,000 to \$35,000 for a bypass; \$12,000 to \$15,000 for a coronary angioplasty, and; \$45,000 to \$50,000 for valve surgery.

OBJECTIVES

The objective of our review was to determine how the Heart Institute used surgery contracts in support of its research mission. Specifically, we determined whether: (1) individuals approved for contract surgeries were on research protocols (approved plan of research) when they received the surgery, (2) medical records demonstrated a correlation between the surgical procedure and the research, and (3) the Heart Institute had a system for recruiting research patients.

RESULTS OF REVIEW

From January 1990 through July 1994, the Heart Institute expended a net of \$9 million for surgeries performed on 346 of its patients by hospitals under contract. Our review of Heart Institute data for the 346 patients, medical records of 73 patients, and discussions with Heart Institute officials disclosed that all the surgeries were not related to research or called for in any research protocol. The Heart Institute arranged for surgeries to be performed on:

-  221 patients, including 24 foreign nationals, as an incentive to have them volunteer for research protocols. The surgeries cost an estimated \$5.1 million (57 percent of the net expenditures). Heart Institute officials advised that the free contract surgeries,² like the surgeries previously provided at the Clinical

¹ Insurance companies reimbursed hospitals about \$2 million for surgeries performed on insured patients during the 4½ year period covered by our review (January 1990 to July 1994). Insurers did not compensate NIH for costs related to diagnostic procedures.

² We use the term "free" surgeries to mean that the surgeries are performed at no cost to the patient. The Heart Institute pays the full cost of surgery for uninsured patients, and the deductible and coinsurance amounts for insured patients.

Center, were the only effective way to attract patients to participate in research that, because of the nature of the research, did not directly benefit the patient. We reviewed the medical records of 45 of the 221 patients and found that 11 of the 45 who had free surgery were not formally enrolled on research protocols.

➡ 125 former patients of the Surgical Branch, including 15 foreign nationals, who received valve replacements or other cardiac surgery costing about \$3.9 million (43 percent of the net expenditures). During our review, the Heart Institute told us it would prefer not to continue treating these patients. According to the Heart Institute, the surgery was provided because of congressional interest in continuing to treat these patients.

While the Heart Institute recruits coronary artery disease patients from 5 Mid-Atlantic states, we found that the Heart Institute did not have written policies regarding the recruitment of patients for research. It did not conduct studies to support its position that free surgery was needed to recruit coronary artery disease patients to research protocols. Also, unlike another NIH institute, the Heart Institute did not have an official policy for the inclusion of foreign nationals in research, although about \$1.4 million (16 percent) of the net expenditures under the contracts were for surgeries provided to 39 foreign nationals.

Since the start of our review, the Heart Institute has taken some significant steps to improve its use of contract surgeries. For instance, the Heart Institute reinstated a requirement that private insurance pay their share of the cost of the surgery, with the Heart Institute paying only the deductibles and coinsurance costs of the insured patients. The Heart Institute also implemented an official policy on admitting foreign nationals for research and routine surgery.

The Department of Health and Human Services is currently seeking ways to re-invent the way it does business. The Department's objective is to look at a range of options to develop more cost effective ways of doing business. As part of the Department's reinvention program (called REGO II), the Secretary has appointed a team of experts led by the Deputy Administrator of the Health Care Financing Administration to review the operations of the Clinical Center.

The REGO II provides an opportunity for the Heart Institute to re-evaluate its use of dwindling research funds for surgery. The Heart Institute should establish formal recruitment strategies for research, taking into account: (1) the need to provide free surgery to obtain research volunteers; (2) the number of American citizens available and suitable for

research; and, (3) the reasonableness of providing continued care to former Surgical Branch patients given the current reduction in Federal resources.

RECOMMENDATIONS AND NIH COMMENTS

We are recommending, in summary, that NIH: (1) in coordination with REGO II activities, conduct a formal study of the Heart Institute's recruitment practices and eliminate the provision of routine surgery to patients not on research protocols including former Surgical Branch patients; (2) develop and implement a formal patient recruitment strategy based on the results of the study; (3) re-emphasize to Heart Institute staff the necessity of adhering to all requirements relative to research protocols in every case involving a patient undergoing research; and (4) ensure that its recently developed policy regarding the inclusion of foreign nationals in research is complied with by all staff.

The NIH, in response to our draft report, generally agreed with all but one of our recommendations. It stated that the Heart Institute wants to continue to see (as outpatients) former Surgical Branch patients who suffer from congenital and valvular heart disease. According to NIH, while no research is conducted on such patients, the clinical training opportunity provided by seeing such patients helps the Heart Institute recruit young cardiologists and retain senior staff cardiologists. The NIH stated the Heart Institute believes it has an obligation to admit and refer for surgery at one of the contract hospitals, patients who may be at high risk if discharged without surgery. As a general comment in its response, the NIH noted that readers should be aware that the Heart Institute's decision to obtain cardiac surgery through contracts resulted in significant savings and scientific benefits. It also noted that it is important to evaluate the potential impact of the report's major recommendations on the ability of the Heart Institute to sustain a clinical cardiology research program. The NIH's comments and OIG's response are discussed in more detail on page 12 of this report. The full text of NIH's comments are included in the Appendix.

TABLE OF CONTENTS

	PAGE
EXECUTIVE SUMMARY	i
BACKGROUND	1
SCOPE OF OUR REVIEW	3
FINDINGS AND RECOMMENDATIONS	5
THE HEART INSTITUTE SHOULD RE-EVALUATE ITS RECRUITMENT OF PATIENTS FOR CORONARY ARTERY DISEASE RESEARCH	5
Free Surgery Provided to 221 Patients	5
Lack of Formal Recruitment Policy or Studies	6
Patients Not on Research Protocols	7
Recruitment of Foreign Nationals	8
Surgery Provided to 125 Former Surgical Branch Patients	9
CONCLUSION AND RECOMMENDATIONS	11
Recommendations, Agency Comments and OIG Response	12
AGENCY COMMENTS	Appendix

INTRODUCTION

BACKGROUND

The NIH is the principal biomedical research agency of the Federal Government. Its mission is to seek to improve the Nation's health by increasing the understanding of processes underlying human health, disability, and disease; advancing knowledge regarding: preventing, detecting, diagnosing, and treating disease; and disseminating research results for critical review and medical application. The Heart Institute is one of NIH's 15 categorical disease institutes that admit patients to the NIH Clinical Center--a research hospital at NIH's headquarters in Bethesda, Maryland. In Fiscal Year 1994, Congress appropriated about \$11 billion for NIH operations including about \$1.28 billion for the Heart Institute.

Patients are normally referred to the NIH by their personal physicians. Since 1990, about 2,500 patients have been admitted to the Heart Institute's Cardiology Branch. Clinical research on patients in the Cardiology Branch includes studying the processes involved in myocardial ischemia, a deficiency of the blood supply to the heart muscle due to obstruction or constriction of the coronary arteries (commonly referred to as coronary artery disease), and hypertrophic cardiomyopathy, a typically chronic or congenital disorder of the heart muscle that may involve excessive development, enlargement, and obstruction. All research takes place at the Clinical Center. Before taking part in research, patients normally are taken off all medications and subjected to Heart Institute screening protocols which encompass standard diagnostic procedures such as, blood tests, urinalysis, chest x-rays, electrocardiograms, exercise stress tests and cardiac catheterizations. These diagnostic procedures, which are usually more extensive than in general practice, help ensure that the patients meet all the criteria of the research protocol and also may provide baseline data for the research protocol. These procedures often represent a necessary component of the research protocol.

To conduct its research on heart disease, the Heart Institute must recruit patients with coronary artery disease and other cardiovascular diseases. The Heart Institute officials told us that the research they performed, which could involve the infusion of drugs through a catheter into the coronary arteries, has no significant therapeutic effect on the patients' health. Thus, there is no direct benefit to patients and this makes recruiting for the research more difficult.

After the patient has participated in diagnostic tests and research, a Cardiology Branch physician may recommend to a committee of Cardiology Branch physicians that a patient receive routine cardiac surgery at one of the four hospitals with which the Institute has a contract. If diagnostic tests show patients are too sick to participate in research they may be sent directly to one of the four hospitals for surgery. Prior to 1990, such surgery was performed at the Heart Institute's Surgical Branch in the Clinical Center. In 1990, the Heart Institute concluded that the surgery necessary to support the Cardiology Branch had been accepted as standard medical procedure and not research and that such surgeries could be

obtained at substantially lower cost through contracts with local hospitals. The Heart Institute officials told us that it cost \$10 million to provide cardiac surgery at the Clinical Center in 1989, while costs at the contract hospitals have been averaging \$2 million a year. Because of these financial and other efficiencies, the Heart Institute closed its Surgical Branch in January 1990 and contracted for heart surgery with the following Washington area hospitals: (1) Georgetown University Hospital; (2) Fairfax Hospital; (3) Washington Hospital Center; and (4) Washington Adventist Hospital.

Under the terms of the contracts with the four hospitals, if a patient did not have health insurance, the Heart Institute paid the full amount of the surgery. If a patient had health insurance, the hospital billed the patient's insurance company and the Heart Institute paid the patient's deductible and coinsurance. This policy changed temporarily in 1993 whereby NIH agreed to pay the entire cost of the surgery for coronary artery disease patients. In 1995 the Heart Institute decided to reinstate its previous policy of having the hospitals bill the patients' insurance company.

To participate in a research protocol, patients must sign a consent form documenting that they are aware of what the study consists of and the risks involved. According to a memorandum from the Chief of the Medical Records Department, when a patient is accepted for research, the patient is counseled and the parameters of the protocol are explained in detail and a formal informed protocol consent form is presented to and signed by the patient. Each patient's medical record should contain an original signed protocol consent form, which identifies the patient, the protocol, the principal investigator, and the treatment plan. The memorandum also states that it is not until protocol consent has been completed that a patient is truly "on protocol," i.e., on a research protocol as distinguished from a screening protocol.

Patients at the Cardiology Branch who were sent to contract hospitals for surgery usually fell into one of three groups:

- Patients with coronary artery disease. These patients normally received, if any surgical therapy is indicated, coronary bypasses or angioplasties.
- Patients with heart valves that were previously installed at NIH and were functioning poorly. The malfunctioning valves were generally replaced.
- Patients with congenital heart disease or with hypertrophic cardiomyopathy. These patients received surgery to correct the unique anatomical abnormality present, or may have needed special pacemakers and or defibrillators (a device which provides an electrical shock to the heart to stop abnormal rhythms).

The surgery contracts, first awarded in 1990, were extended through August 1995 at a total authorization of about \$10.7 million. According to the records we reviewed, 346 patients

received 427 surgical procedures costing about \$9 million as of July 1994 at the four contract hospitals. The applicable procedures were:

- 117 coronary bypasses and 97 angioplasties for patients with coronary artery disease;
- 105 artificial heart valve replacement and repairs; and,
- 108 surgeries to repair congenital, chronic and other heart problems.

The cost for these procedures differed based on patients' medical conditions and type of procedure. We noted that costs usually ranged between: \$30,000 to \$35,000 for a bypass; \$12,000 to \$15,000 for a coronary angioplasty, and; \$45,000 to \$50,000 for valve surgery.

The Department of Health and Human Services is currently seeking ways to re-invent the way it does business in order to conserve diminishing Federal resources. As part of the Department's reinvention program (called REGO II), the Secretary has appointed a team of experts led by the Deputy Administrator of the Health Care Financing Administration to review the operations of the Clinical Center. Their objective is to look at a range of options to develop more cost-effective ways of doing business.

SCOPE OF REVIEW

The objective of our review was to determine how the Heart Institute used surgery contracts in support of its research mission. Specifically, we determined whether: (1) individuals approved for contract surgeries were on research protocols, (2) medical records demonstrated a correlation between the surgical procedure and the research, and (3) the Heart Institute had a system for recruiting research patients.

We reviewed the Heart Institute's contracts with the four hospitals for cardiac surgery services, and a listing of 346 cardiology patients who were referred to the four hospitals for surgery by the Heart Institute's Cardiology Branch during the period January 1990 through July 1994. For all 346 patients, we determined the hospital to which the patient was referred, date referred, surgical procedure performed and referring physician.

We reviewed the medical records of 73 patients, including all 39 foreign nationals³ that received surgery under the contracts. We reviewed the records of all foreign nationals to determine the extent to which they made use of contract surgery and the cost of such surgeries. We reviewed protocols at the Clinical Center's Medical Records Department, clinical records at the Heart Institute, and pertinent correspondence for the 73 patients. Interviews with Heart Institute program officials and contracting officials were held

³ These patients were selected for review based on an NIH-provided computer printout, which showed they did not have Social Security Numbers and were not United States citizens. The admitting forms, correspondence and notes in these patients' medical records also indicated they were citizens of a foreign country. According to the admitting forms, 3 of the 39 foreign nationals had permanent visas.

throughout our review. We also reviewed the PHS Act and applicable regulations. We were assisted in our review by our medical advisor, a physician.

We attempted to review the Heart Institute's official recruitment policies but were told that none existed in writing. The Heart Institute provided us form letters that were sent to as many as 5,600 physicians in the five States of Virginia, Maryland, Pennsylvania, Delaware, and West Virginia seeking their cooperation in recruiting patient volunteers for research.

Our review was conducted at the NIH Clinical Center and in accordance with generally accepted government auditing standards.

FINDINGS AND RECOMMENDATIONS

THE HEART INSTITUTE SHOULD RE-EVALUATE ITS RECRUITMENT OF PATIENTS FOR CORONARY ARTERY DISEASE RESEARCH

All components of the Federal Government have been asked to reinvent the way they do business. Consistent with this, the Heart Institute needs to re-evaluate the way it recruits patients for research. From 1990 through July 1994, the Heart Institute expended about \$9 million on free surgeries to 346 patients. About \$5.1 million of this amount was spent to recruit 221 patients to volunteer for research protocols primarily investigating coronary artery disease. We determined that the Heart Institute had no formal patient recruitment policies, and some of the patients recruited were not on research protocols at the time they received surgery. The remaining \$3.9 million was spent on providing surgery to 125 former Surgical Branch patients who were not participating in current research protocols. The Heart Institute was following a policy of replacing valves previously inserted under research protocols. About \$1.4 million of the \$9 million was spent on foreign nationals, again in the absence of an official recruitment policy for foreign nationals.

Free Surgery Provided to 221 Patients

About \$5.1 million or 57 percent of the contract funds expended on the surgeries involved 221 individuals who were recruited for research after the Surgical Branch was closed in 1990. Our review of the medical records for 45 of the 221 individuals and discussions with Heart Institute officials disclosed that the free surgeries were provided, in part, as a benefit for patients who volunteered for research that otherwise would be of no benefit to the patient. Officials also told us they thought it was professionally unethical not to treat patients who were in serious need of surgery that might otherwise not be available to them. The Heart Institute officials justified this policy as being the only effective way to attract patients with coronary artery disease to research.

We question the practice of using research funds in this way on the basis that the Heart Institute:

- ✓ Did not have a formal written patient recruitment policy, and had not conducted any studies to adequately justify the need for the use of free surgery to recruit patients.
- ✓ Provided free surgery to 11 patients (of the 45 patients whose medical records we reviewed) who were not formally on a research protocol at the time they received the surgery, i.e., had not signed a research protocol consent form.

- ✓ Expended \$750,000 providing surgery to 24 foreign nationals (included in our review of 45 patients) without having a policy regarding their inclusion in research.

Lack of Formal Recruitment Policy or Studies

In response to our questions regarding its recruitment efforts, Heart Institute officials told us they did not have an official written recruitment policy, had not tried other alternative methods of recruitment, had not conducted a study to determine the feasibility of alternative recruitment methods, and did not have a written policy for inclusion of foreign nationals in research.

The officials informed us they have recruited patients from local health maintenance organizations and have mass mailed recruitment letters to physicians in 5 Mid-Atlantic States. The letters request the physicians to refer patients with coronary artery disease for research. Heart Institute officials provided us with two such letters. One letter, dated December 10, 1991 was mailed to about 5,600 physicians. The second letter, dated September 30, 1993, was mailed to about 1,000 physicians.

The September 30, 1993 letter identified the types of free services that were offered at the Clinical Center to patient volunteers. They included such diagnostic tests as cardiac catheterization, positron emission tomography (PET scan), and magnetic resonance imaging. The letter also identified the free surgical procedures that would be performed at the four hospitals under contract. The surgeries included coronary bypass surgeries and coronary angioplasty.

The Heart Institute officials stated that diagnostic procedures were needed to ensure that patients qualified for research protocols. The offer of free surgery was needed to recruit patients because coronary artery disease is common and routine treatment is widely available at many community hospitals. Also, according to the Heart Institute, it would be difficult to recruit such patients for research protocols if surgery was not available because the research does not benefit the patients. They noted that, for the most part, the policy of offering free care resulted in attracting patients, including foreign nationals, who were uninsured.

In response to our question regarding alternative research sites, Heart Institute officials told us conducting its research at community hospitals, where there may be an ample supply of patients about to have surgery, was not a practical research alternative to the NIH Clinical Center. They said that space, time, and equipment was not always available for research use at these sites and that there was little opportunity for interaction with other NIH researchers. The officials also said there was no incentive for private physicians and patients to cooperate with Heart Institute researchers and, as a rule, community hospitals generally do not want their name connected with research on patients.

Patients Not on Research Protocols

Eleven of the 45 patients whose medical files we reviewed were not on a research protocol. The 11 patients (including 4 foreign nationals) were coronary artery disease patients, and patients with congenital heart defects. They had bypasses and angioplasties performed and one patient had congenital defects repaired. We could only find consent forms for screening or standard diagnostic procedures. The official medical records as well as records kept at the Heart Institute did not contain signed consent forms for research protocols.

According to a Heart Institute official, these patients did not take part in research protocols because NIH found the patients were either not good candidates for research (individuals having left main artery blockage), or they were otherwise too sick to participate. The Heart Institute official also stated that:

"...physicians in the Cardiology Branch believed it was professionally, ethically, and probably, legally necessary to provide surgery (not to abandon) for patients who were at high risk without surgery (irrespective of whether they were eligible to enter a research protocol) and who frequently had no other means to obtain the needed surgery."

Also, according to a Heart Institute official, 10 of the 11 patients did participate in research studies that were described in approved research protocols. The Heart Institute told us in the years these patients were admitted to the Clinical Center (1990 and 1991), the Heart Institute did not always document (obtain written consent for research) when it transferred certain patients from screening to research protocols. The Heart Institute said that the research was always explained to the patient. Another official showed us researchers' notes and logs for the 10 indicating that imaging and other studies were performed on these patients. These notes showed the patients had PET, thallium or technetium scans, echo cardiograms, and standard diagnostic procedures. According to Heart Institute officials, these data were used in studies evaluating the diagnostic value of these different procedures or to study the natural history of heart disease. The official told us that since 1991, patients taking part in such studies have been officially placed in research protocols.

Based on the documentation available in the patients' official medical records, we were unable to determine if any of the 11 patients could have participated in research protocols, as indicated by the Heart Institute official. If the patients did so, the Heart Institute failed to obtain a signed research consent form as required for patients participating in research. Research involving human subjects requires a complete written description of the proposed research (a research protocol). This proposed research must be approved by an institutional review board, whose primary responsibility is to protect the rights and safeguard the welfare of human research subjects. The research protocol must contain various elements to describe what is to be done, how the subjects are selected, how their safety is ensured, and an informed consent document, as well as the scientific justification for the activity. The research protocol must also be approved by Clinical Center and institute officials. A Heart

Institute official said there were properly approved research protocols for all of the procedures that were performed. The failure was not ensuring that the 11 patients signed research protocol consent forms in addition to the screening protocol consent forms that were signed.

Recruitment of Foreign Nationals

Twenty-four of the 45 patients who volunteered for research and received free surgery offered by the Heart Institute were foreign nationals. The medical records of four of the foreign nationals did not contain signed research consent forms.

The Heart Institute did not have a formal policy for the inclusion of foreign nationals in research. We also noted that the Heart Institute admitted the foreign nationals into their research program, and provided them free surgery, without first expanding recruiting efforts in the United States beyond the 5-State area surrounding Washington, D.C., thus providing little assurance that U.S. citizens were given top priority. A Heart Institute official told us that foreign nationals were included in the surgery program because it was difficult to recruit United States citizens. He indicated that in some cases foreign nationals would be attracted to the surgery program because of the quality of care which may not be available in their country of origin.

Based on our review of these patients' medical records, it appears many of the 24 foreign nationals came to NIH after they or their physicians became aware of free surgery in return for participation in research. Their physicians referred them to physicians in the United States who, in turn, referred them to NIH. We also noted a situation where a physician from Pakistan referred patients directly to a staff cardiologist at the Heart Institute.

Following are examples of the information we obtained from the official medical records of foreign nationals who received services under the NIH contracts.

- A patient from Pakistan was admitted to the Cardiology Branch on a screening protocol on December 15, 1990. He was referred to a contract hospital for a coronary artery bypass graft 4 days later on December 19, 1990. The patient apparently returned to Pakistan (his medical record stated that the patient would be followed up by his private physician in Pakistan). The Heart Institute showed us data indicating he participated in imaging studies. We could not find a protocol consent form in the medical record that indicated that this patient participated in a research protocol. The NIH paid the contract hospital \$34,177 for this individual's surgery.
- A patient from Cuba, listed on NIH medical records as a physician, was admitted to the Cardiology Branch on February 26, 1994, and referred for surgery on March 14, 1994. The patient participated in a Heart Institute research protocol lasting between 2 to 3 hours. The NIH paid the contract hospital \$35,000 for this patient's surgery.

- A patient from India, listed on NIH medical records as a businessman on a holiday in the United States traveling on a tourist class visa, was admitted to the Cardiology Branch on August 1, 1992. The patient participated in about 2 to 3 hours of research and was referred for surgery on August 31, 1992. The NIH paid the contract hospital \$32,434 for this patient's surgery.

In contrast to the Heart Institute's lack of a formal policy on foreign nationals, the National Cancer Institute (NCI), does have such a formal recruitment policy which emphasizes that American citizens be given priority in their research programs. At NCI, only the Clinical Director or Institute Director, except in an emergency, can admit a foreign national. In a September 1988 memorandum to the acting Clinical Director, the NCI Deputy Clinical Director discussed the problems in treating foreign nationals and stated that it is NCI's policy to provide an absolute priority to U.S. citizens and permanent residents to accession to NCI's therapy protocols. The NCI memorandum stated that the administration of its protocols be fair and be perceived as fair by Congress and the public-at-large.

The NCI memorandum also stated that when it is determined that the generation of knowledge may depend on admitting a certain number of foreign nationals, such admissions are permitted provided that there is an approved protocol and when it can be documented that there is a lack of availability of eligible U.S. citizens to complete the protocol. It further stated: "...the medical and humanitarian needs of a very high percentage of foreign nationals who apply for therapy at the Clinical Center can be handled by nongovernment institutions throughout the country."

After our audit field work was completed, the Heart Institute established a written policy for the inclusion of foreign nationals in research. According to this policy, which became effective January 3, 1995, U.S. citizens are to be given the highest priority for clinical protocols. The Clinical Director must be notified of all instances where a foreign national may be admitted and given a reason as to why such admission is required. The Clinical Director will independently monitor the number of foreign nationals admitted under a clinical protocol and report semi-annually to the Scientific Director and Institute Director.

Surgery Provided to 125 Former Surgical Branch Patients

About \$3.9 million, or about 43 percent of the contract funds expended on routine surgeries, involved 125 former Surgical Branch patients who in the period from 1960 to 1980 took part in research. Such patients no longer are participating in current research. Funds used to provide surgeries to patients not on current research protocols do not, in our opinion, support the Heart Institute's research mission. The Heart Institute officials stated that it had been the policy of the Surgery Branch from its inception to continue to see its past patients approximately annually both to collect long-term data and to replace or repair formerly experimental heart valves that had been originally inserted by Heart Institute staff for research protocols. This policy was continued after the Surgery Branch was closed, in part because of congressional interest and in part because of the existing long-term relationships with the patients.

Our review of the medical records of 73 patients who were provided surgery under the Heart Institute contracts revealed that 28 patients, including 15 foreign nationals, were former Surgical Branch patients who returned to NIH for replacement valves or other heart surgery. Nineteen of the 28 had NIH installed heart valves repaired/replaced and 9 returned for either bypasses, angioplasties or other heart surgery. Although these patients were once on research protocols, none of the 28 were on a research protocol when they received the surgery.

The 15 foreign nationals received surgeries costing about \$650,000. Following are examples of the information we obtained from the official medical records of 2 of the 15 foreign nationals who were former Surgical Branch patients.

- A patient with valve disease, from India, whose sister was the referring doctor, was first seen at NIH in June 1976, for aortic valve replacement (AVR) and mitral valve replacements (MVR). The patient returned to NIH for a variety of diagnostic tests from 1984 to 1993. Several of her admissions were charged to a standard care/follow-up protocol; a copy of which was not in the medical record. On November 16, 1993, the patient was referred to a contract hospital for a repeat of AVR, MVR as well as a Tricuspid Valvuloplasty at a cost estimated at \$75,766. Throughout the patient's history at NIH, which spanned almost 20 years, there was no evidence of a signed protocol consent form in the patient's medical record.
- A patient from Bolivia with congenital heart problems was first seen at NIH in November 1971. She had various procedures to repair and replace defective heart valves--tricuspid valve replacement (TVR) and MVR. She also had a pacemaker installed at NIH. All of these procedures took place over a 17-year period. She was then referred to a contract hospital under the NIH contract for treatment of an infection related to pacemaker wires on December 20, 1993. On July 20, 1994, she was again referred to the contract hospital for a repeat of TVR and MVR. She also had a pacemaker installed at the hospital. The total cost of the TVR and MVR procedures provided under the contract is estimated at \$80,528. We could not find any evidence in the medical record that the patient had enrolled in a research protocol at any point in time during this patient's care at NIH.

According to the Heart Institute, patients in the above two examples began their participation in research in the 1970s when the policy regarding protocols was different than today. Currently, Federal regulations require signed consent forms for patients on research protocols. The Heart Institute agreed that no research was conducted on these 28 former Surgical Branch patients when they received surgery at the four contract hospitals. Furthermore, the official stated that there were a total of 125 such patients who received surgery under one or more of the contracts for heart valve replacement and other surgery. The official estimated that about \$3.9 million was spent to provide routine surgeries to the 125 former patients. The official also said that these patients had participated in research on valves in earlier years.

According to a Heart Institute cardiologist, former valve patients are not suitable for current coronary artery disease research protocols. The Heart Institute did not intend to continue this policy of caring for former valve patients after the closure of the Surgical Branch in 1990 because it was no longer doing research on valve patients. However, according to the Heart Institute's Director, he decided to continue treating these patients after receiving phone calls and letters from several congressmen requesting that the Heart Institute consider the continued treatment of former patients even though not related to any research being conducted by the Heart Institute.

CONCLUSIONS AND RECOMMENDATIONS

The Heart Institute, whose primary function is research on heart disease, spent about \$9 million of its funds in the period 1990-1994 to provide routine cardiac surgery to 346 individuals, including 39 foreign nationals. About 57 percent of the funds were used to attract patients to research protocols, and 43 percent of the funds were used to provide surgery to former Surgical Branch patients who were not involved in current research.

We question the practice of spending research funds for free surgery in the absence of studies supporting the need for an incentive to attract U.S. citizens to volunteer for research. While the offer of free surgery has been somewhat successful in recruiting patients for research, the Heart Institute should attempt alternative means of recruitment. The potential exists for lowering the costs of research by limiting the benefit to the patient to the costs of diagnostic procedures at the Clinical Center where the actual research is performed. Currently, in addition to these tests, procedures costing from \$12,000 to \$50,000 are provided in exchange for what might, in most cases, be several hours of research.

The Heart Institute needs to establish formal recruitment policies for research, taking into account the need for research volunteers, the number of American citizens available and suitable for research, and the reasonableness of providing continued care to former Surgical Branch patients given the current reduction in Federal resources. Expansion of the 5-State recruitment base as well as the use of outside experts experienced in recruitment to alert the general population of heart patients to the health benefits of involvement in NIH supported research, including the expertise of NIH physicians, should be considered. An added benefit of expansion of the recruitment base would be the potential for a more diverse research population.

All components of the Federal Government have been asked to reinvent the way they do business. The Department of Health and Human Services is no exception. In this regard, the Secretary, as part of REGO II, has appointed a team of experts led by the Deputy Administrator of the Health Care Financing Administration to review the operations of the Clinical Center. Their objective is to look at a range of options to develop more cost-effective ways of doing business. We believe the cost effectiveness of the Heart Institute's practice of providing free standard care surgeries to patients and former patients, including foreign nationals, should be included in this review.

Recommendations, Agency Response and OIG Comments

We recommend that the NIH:

1. In coordination with REGO II activities, conduct a formal study of the Heart Institute's recruitment practices with an aim of:
 - a) exploring alternative methods of recruiting patients, including expansion of the recruitment area within the United States (beyond the 5-State area).

Agency Comment: The NIH agreed and stated that NHLBI will seriously explore alternative mechanisms that can be tested in a way that will not harm clinical research in the Cardiology Branch.

- b) eliminating the provision of routine surgery to treat pre-existing conditions unrelated to research unless demonstrably critical to valuable research effort.

Agency Comment: The NIH stated that because of a substantial decline in the number of coronary artery disease (CAD) patients, the present difficulty in recruiting CAD patients can only be exacerbated by ceasing to provide surgery for those who need it. However, NIH stated that staff of the Cardiology Branch, in consultation with the Clinical Center staff, is seeking to develop an alternative approach to recruitment of CAD patients that will test the need to provide surgery (as an incentive to participate in research). According to the Heart Institute, the challenge is to develop and test an approach that will not destroy the already fragile research program. It stated that it would not take much to cause the senior staff to accept much more lucrative positions in academia.

OIG RESPONSE: We believe that an alternative approach to recruiting CAD patients should be explored. During our audit, we discussed with the Heart Institute the possibility of conducting its research at community hospitals where there was not a shortage of CAD patients. We believe that this is one approach that should be considered.

- c) eliminating the provision of surgery to treat former Surgical Branch patients.

Agency Comment: The NIH did not concur. It now believes it is essential to continue to see these patients in its outpatient clinic so it can attract junior cardiologists to NIH and provide training to other staff. It stated that these former patients (with congenital and valvular heart disease) are an essential component of the Heart Institute's training protocol. The availability of such patients help attract junior cardiologists to NIH and also provide the only opportunity for senior

cardiologists to see such patients. It also stated that the NIH assumed an obligation to admit and provide surgery to such patients that may be at high risk if discharged without surgery.

OIG RESPONSE: We disagree with NIH's position and continue to believe that NIH should not admit such patients for routine care. Our review of the medical records for 28 former Surgical Branch patients (which included 15 foreign nationals) who returned to NIH for additional surgery indicated that none were on a research protocol at the time they received the routine surgery. Thus these surgeries did not support the research mission of the Cardiology Branch. Our review of the contracts with four Washington area hospitals did not indicate that such contracts were for the purpose of recruiting young cardiologists or for their training once recruited. Also, no where in the medical records of the 28 former patients did it indicate that they came back to NIH because they had no other surgical alternative. We believe NIH should encourage former patients to seek routine care at community hospitals where such care is covered by private and public health insurance.

2. Develop and implement a formal patient recruitment strategy based on the results of the study.

Agency Comment: The NIH agreed.

3. Re-emphasize to Heart Institute staff the necessity of adhering to all requirements relative to research protocols in every case involving a patient undergoing research prior to surgery.

Agency Comment: The NIH agreed and stated that this has been the practice in the Cardiology Branch and throughout the Heart Institute for several years prior to this audit and will continue to be enforced. The NIH officials stated that patients without signed research protocol consent forms identified in the audit were not an uncommon occurrence prior to 1991. They also stated that in every case the research protocol was fully explained to the patient and a consent form for diagnostic procedures was administered and signed.

OIG RESPONSE: Research conducted on patients without legally sufficient consent (regardless of verbal explanations) is a violation of government regulations (Title 45, Code of Federal Regulations, Part 46). This regulation states that the investigator shall seek consent on the part of the patient only under circumstances that provide the patient with "sufficient opportunity to consider" whether or not to participate in the research protocol. With rare exception, a verbal explanation of what the protocol consists of falls short of meeting this requirement.

4. Ensure that its recently developed written policy regarding the inclusion of foreign nationals in research is complied with by all staff.

Agency Comment: The Heart Institute agreed and stated that this is being done and will continue to be done. The policy states that foreign nationals will be admitted as patients only when suitable American patients are not obtainable and must be approved by the NHLBI Clinical Director. The policy also states that a report on foreign national patients is to be submitted to and reviewed by the Scientific Director and Institute Director every 6 months.

As a general comment in its response, NIH noted that readers of this report should be aware that the Heart Institute's decision to obtain cardiac surgery through contracts resulted in significant savings and scientific benefits. It also noted that it is important to evaluate the potential impact of the report's major recommendations on the ability of the Heart Institute to sustain a clinical cardiology research program.

APPENDIX



National Institutes of Health
Bethesda, Maryland 20892

OCT 13 1995

TO: Ms. June Gibbs Brown, Inspector General (IG)

FROM: Director, NIH

SUBJECT: Audit of the National Institutes of Health's (NIH) Use of Heart Surgery Contracts with Private Hospitals (A-15-94-00022)

We appreciate the opportunity to provide comments on the draft audit report on the use of contracts by the NIH's National Heart, Lung, and Blood Institute (NHLBI) to obtain routine cardiac surgery, which accompanied your September 11 memorandum.

The draft report and the interactions between the IG audit team and officials of the NHLBI during its preparation have been useful in bringing another perspective to an issue that has been intensively studied by the NHLBI for more than six years. As you noted, the NHLBI has already complied with and begun to explore the recommendations outlined in the draft report.

Our comments are detailed in the attached document; however, I wish to underscore the importance of addressing two points so that the information and recommendations of the audit are presented within a more complete and balanced context of the research mission of the NHLBI and NIH. As currently written, the draft executive summary and report do not provide the historical, institutional, and scientific perspective on the management of the cardiac surgery activities. In particular, readers are not made aware of the fact that after 35 years of surgery performed in the Clinical Center, the NHLBI made a critical management decision to obtain cardiac surgery by contract, and that this decision resulted in very significant fiscal and scientific benefits. In fact, the surgery contracts have been enormously cost-effective. While this certainly does not negate additional efforts for improvement, we believe this information should be included in the final report. Second, it is important to evaluate the potential impact that the report's major recommendations might have on important research on coronary artery disease, in particular, and more generally, on the ability of the NHLBI to sustain a clinical cardiology research program. Since no recommendations should be viewed in isolation of their impact, this additional information is essential to the full understanding of the complex issues at hand. These points are explained in more detail in the attachment.

We hope that our comments will be of assistance to you. Should you or your staff have any questions, please do not hesitate to contact Dr. Claude Lenfant, Director, NHLBI, at (301)496-5166.

Attachment

IS	✓
ASAC	_____
FDSD	_____
DEG-AS	_____
DEG-EI	_____
DEG-OI	_____
DIG-MP	_____
AIG-CFAA	_____
OIG/IG	_____
EXSEC	_____
DATE SENT	10/23

Harold Varnus
Harold Varnus, M.D.

for

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OFFICE OF THE INSPECTOR GENERAL

NIH COMMENTS ON THE DRAFT REPORT: Audit of the National Institutes of Health's Use of Heart Surgery Contracts with Private Hospitals (A-15-94-00022)

Decision to Contract Out Cardiac Surgery

From the creation of the NHLBI intramural research program in the early 1950s, the Surgery Branch conducted innovative research at the forefront of its field. From its inception (as an offshoot of the Surgery Branch), the Cardiology Branch and the Surgery Branch worked closely together; all of the patients admitted to the Surgery Branch protocols were first screened by the Cardiology Branch and Cardiology Branch patients were admitted to the Surgery Branch when cardiac surgery was medically indicated. The staff of both Branches believed strongly that neither could function without the other. Surgery Branch patients had to have a full cardiology workup to ensure that they were appropriate subjects for surgical research and cardiology care following surgery; and the Cardiology Branch depended on the surgeons to provide medically indicated cardiac surgery to its patients.

By the late 1980s, however, the situation had changed: (a) the Surgery Branch was judged by external expert peer review as no longer being at the forefront of cardiovascular research, (b) it became impossible to recruit excellent research cardiac surgeons at government salaries, and (c) most of the patients receiving cardiac surgery were on Cardiology Branch protocols. The NHLBI Director and Scientific Director made the difficult decision to close the Surgery Branch and to provide the necessary surgical support to the Cardiology Branch through contracts with local hospitals. This decision was met with great apprehension by the Cardiology Branch staff. Without immediate surgical backup, they had to stop all research on angioplasty, and there was concern about their ability to develop the necessary close relationships with the contract surgeons that they had with their NHLBI colleagues. There was a major concern that it would be much more difficult to recruit patients for their research protocols and that the absence of full cardiology and cardiac surgery services would make it difficult to maintain the clinical environment necessary to attract and train junior staff that are essential to, and an integral part of the clinical research program.

Fiscal and Scientific Impact of Decision

The Surgery Branch was closed in 1990, and both the positive and negative expectations about the impact of this decision were fulfilled.

	FY 1989	FY 1994	Savings
Cardiac Surgery Costs	\$10.3M	\$ 1.5M*	\$ 9M*
Surgery Branch & Cardiology Branch Costs	\$17.8M	\$ 9.5M*	\$ 8M*

* dollars unadjusted for inflation

As shown in the above table, in FY 1989, the last full year of surgery at the Clinical Center, cardiac surgery in the Clinical Center cost \$10.3 million. In FY 1994, the cost of cardiac surgery through the contract hospitals was \$1.5 million, i.e. almost \$9 million saved in each year even when comparing 1989 dollars to 1994 dollars. The combined Clinical Center costs of the Surgery and Cardiology Branches were \$17.8 million in FY 1989 and the Clinical Center plus surgery contract costs of the Cardiology Branch were \$9.5 million in FY 1994, a savings of more than \$8 million without adjusting for inflation.

In addition to the \$8 to 9 million (unadjusted for inflation) savings in hospital costs, closing the Surgery Branch released for other purposes \$2.1 million in salaries and benefits and laboratory operating costs per year, 25 FTEs, laboratory space and one entire patient care unit in the Clinical Center. The residual costs of the surgery contracts, \$1.5 million in FY 1994 and about \$2 million per year for the 5 years of the contracts, although not insignificant, are certainly quite small compared to enormous savings already accomplished by the NHLBI by initiating the contracts.

Impact of Audit Recommendations

The report addresses the residual \$1.5 million in annual cardiac surgery costs. What might be the cost of this saving?

■ Clinical skills and research programs

We know that stopping surgery at the Clinical Center caused one senior cardiologist to resign because he could not continue his research efforts to develop improved angioplasty techniques. The other senior cardiologists had to make individual arrangements to perform angioplasty at local hospitals because it is essential that they maintain their skills in invasive cardiology. We also know that the lack of a full clinical service has caused outstanding junior cardiologists to pursue their research training at other institutions. It is not possible to initiate a cardiology fellowship program at the NIH as has been successfully done for hematology. Although probably not due solely to the closing of the Surgery Branch, inpatient days for the Cardiology Branch have fallen from 4,629 (or 9,270 for the Cardiology and Surgery Branches combined) in FY 1989 to 2,752 in FY 1994. This may be the minimum number of patients that can sustain clinical cardiology.

■ Recruitment of new patients

The surgery contract costs are approximately equally divided between two groups: (a) patients newly recruited for current research protocols, principally for research on coronary artery disease, who are provided cardiac surgery (if deemed necessary by the Cardiology Branch) at no cost to them over and above that covered by insurance, and (b) previous research patients of the Surgery Branch who are not participating in a current research protocol. One of the major recommendations of the draft report is for the NHLBI to conduct an "experiment" to determine (1) whether it is necessary for recruiting new patients to provide surgery that is not specifically related to the research protocol and (2) that surgery no longer be provided to former Surgery Branch patients.

We believe it is essential to maintain vigorous clinical cardiology research, in general, and, more specifically, research on coronary artery disease. Therefore, we must proceed cautiously. For 40 years, cardiology research patients have received surgery at no cost to them—for 35 years at great expense in the Clinical Center and for five years at very substantially less expense through the surgery contracts. We need these patients for research, and we need these patients for training young cardiologists, including those who may not be involved in clinical research. The substantial decline in cardiology patients over the last few years has probably been driven by the growth of managed health care (for example, neither Group Health Association, which had been the single largest source of patients, nor any other HMO will now send patients to the Cardiology Branch), and the ability of many cardiologists and surgeons to perform procedures that previously could be obtained only at a few institutions such as the Clinical Center. Thus, it seems reasonable that the present difficulty in recruiting patients can only be exacerbated by ceasing to provide surgery for those who need it.

However, the staff of the Cardiology Branch, in consultation with the Clinical Center staff, is seeking to develop an alternative approach to recruitment of coronary artery disease patients that will test the need to provide surgery. The challenge is to develop and test an approach that will not destroy the already fragile clinical research program. It will not take much to cause the senior cardiologists to accept much more lucrative positions in academia.

■ Treatment of former Surgery Branch patients

Although the former Surgery Branch patients do not contribute to current research, they provide a cadre of patients that is essential for clinical training purposes. Mostly, these patients suffer from congenital and valvular heart disease, conditions for which there are no current research protocols, and therefore, they provide the only opportunity for our staff to see such patients. Most have had cardiac valves replaced and studying such patients is an important aspect of cardiology. Indeed, cardiology and cardiac surgery are so intertwined that it is not certain that clinical cardiology can be maintained in the absence of a contract surgery program. We believe that we can neither fulfill our training function, attract junior cardiologists, nor retain our senior cardiologists unless, at a minimum, we continue to see the former Surgery Branch patients in the outpatient clinic (about 10 per week) as an essential component of our current training protocol. We feel we would then be obligated to admit to the Clinical Center any patient whom the attending cardiologists thought was facing an acute problem. This might necessitate that surgery be provided, at the very least, for those patients who would be at high risk if discharged without surgery.

Many of the former Surgery Branch patients have been seen for more than 20-30 years at the Clinical Center, initially because the research protocols required that the consequences of the experimental surgery be followed and that failed valves be replaced and studied. This has unavoidably created a strong connection, verging on dependency, between the patients and the NHLBI staff, especially for those patients who have no other physician or cardiologist and are often uninsured. Some of these patients will die if surgery is not provided. Has the NIH assumed an obligation to continue to provide surgery to such patients, remembering that they had contributed

substantially to important surgical research? The senior cardiology staff believes the answer is "yes," but we will ask a bioethics group to consider these questions before making a final decision. In considering the pros and cons of these issues, we should not lose sight of the enormous savings that the NHLBI has already accomplished.

Two other conclusions and a recommendation of the draft report require brief comment and response.

■ **Recruitment of foreign nationals**

The Cardiology Branch would much prefer their patients to be American citizens or permanent residents in the United States. It is easier for the patients to return to the NIH and it is easier for the NHLBI scientists to maintain contact with the patients and their physicians, if any. However, sometimes the disease under study, but more recently the difficulty in recruiting patients, necessitates recruitment of foreign patients. It should be remembered that the NIH is a research institution, so that the benefits of the research (which have been substantial for the protocols utilizing most of the foreign patients) are available to all, but especially Americans because of the rapidity with which research discoveries move into practice. Americans benefit when recruitment of foreign nationals accelerates the research. Nonetheless, as the draft report states, the policy that has always been practiced is now in writing: foreign nationals are admitted as patients only when suitable American patients are not obtainable, admission of foreign nationals must be approved by the NHLBI Clinical Director, and a report on foreign national patients is submitted to and reviewed by the Scientific Director and Institute Director every 6 months.

■ **Informed research protocol consent**

For approximately the last three years, every patient on a research protocol has signed an informed research protocol consent. Those identified in the draft report who were on research protocols without a signed consent form date back to 1991 or earlier when this was not uncommon throughout the NIH. Even those patients had signed a consent form to allow the diagnostic screening procedures to be carried out. And, in every case, the research protocol was fully explained to the patient by the principal investigator or another informed participant (usually this is noted on the screening protocol consent form). The important fact is that the patients were fully informed when they entered the research protocol, even though it was not always adequately documented. However, this "deficiency" was not unique to the patients of the Cardiology Branch, was not related in any way to the surgery contract issue, and was corrected well before the audit of the surgery contracts began.

■ **Patients not on research protocols**

The draft report mentions patients who were referred to surgery even though they did not participate in research. These patients fall into two groups. Some were diagnostically exposed to PET and thallium scans as part of the screening protocol and found not to be appropriate for any of the research protocols. However, one research protocol (and a very successful one) was essentially a comparison of the diagnostic

value of thallium and PET scans. Thus, these patients provided valuable research data just by participating in the screening protocol. Other patients were found to be too sick, or otherwise inappropriate, for a research protocol. Under the terms of the recruitment policy, such patients were provided surgery if needed.

Summary

- The draft report recommends the NHLBI reemphasize that all patients entering a research protocol sign the appropriate consent form. This had been the practice in the Cardiology Branch and throughout the NHLBI for several years before the audit began and will continue to be enforced.
- The draft report recommends that the NHLBI ensure all staff comply with its written policy on admission of foreign patients. This is being done and will continue to be done.
- The draft report recommends a formal study to explore alternative recruitment policies to increase the number of patients from the United States and eliminate provision of routine surgery unless demonstrably critical to valuable research. The NHLBI will seriously explore alternative mechanisms that can be tested in a way that will not, in the process, decimate clinical research in the Cardiology Branch.
- The draft report recommends that surgery no longer be provided to former Surgery Branch patients. The NHLBI believes that to maintain clinical cardiology it is essential to continue to see these patients in the outpatient clinic, to admit to the Clinical Center those whom it would not be safe to send home, and probably to provide surgery for those in this group who need it acutely. The NHLBI will explore the relative advantages and disadvantages to the clinical research program and its obligations to longtime patients before deciding to stop providing surgery to the other former Surgery Branch patients.

We strongly believe that those issues raised by the audit that have not already been satisfied are minor in comparison to the enormous gains derived by closing the Surgery Branch and continuing to provide surgery at no cost to the patients through the surgery contracts with private hospitals. Replacing free surgery in the Clinical Center by free surgery through contracts released more than \$10 million a year, 25 FTEs and substantial laboratory and hospital space for new research. The comparatively small additional savings to be gained by eliminating or modifying this policy must be carefully balanced against the possibility that any change would stop most of the clinical research activities of the Cardiology Branch.