



OCT 30 2001

Office of Audit Services  
Region I  
John F. Kennedy Federal Building  
Boston, MA 02203  
(617) 565-2684

CIN: A-01-01-01500

Dr. Steven Freedman, Program Director  
General Clinical Research Center  
Beth Israel Deaconess Medical Center  
330 Brookline Avenue, GZ-800  
Boston, MA 02215

Dear Dr. Freedman:

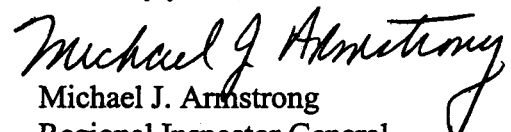
Enclosed are two copies of the U.S. Department of Health and Human Services (HHS), Office of Inspector General, Office of Audit Services' (OAS) report entitled "Audit of the General Clinical Research Center At Beth Israel Deaconess Medical Center for Fiscal Year Ending November 30, 1999." Should you have any questions or comments concerning the matters commented on this report, please direct them to the HHS official named below.

Final determination as to actions taken on all matters reported will be made by the HHS action official named below. We request that you respond to the HHS action official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

In accordance with the principles of the Freedom of information Act (5 U.S.C 552, as amended by Public Law 104-231), OIG, OAS reports issued to Department's grantees and contractors are made available to members of the press and general public to the extent information therein is not subject to exemptions in the Act which the Department chooses to exercise. (See 45 CFR Part 5.)

To facilitate identification, please refer to Common Identification Number A-01-01-01500 in all correspondence relating to this report.

Sincerely yours,

  
Michael J. Armstrong  
Regional Inspector General  
for Audit Services

Enclosures – as stated

**Direct Reply to HHS Action Official:**  
Director, Division of Management Assessment  
Room 1B-05 Building 31  
National Institutes of Health  
6100 Executive Blvd. Room 6B05  
Rockville, Maryland 20892

**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**AUDIT OF THE GENERAL CLINICAL  
RESEARCH CENTER AT BETH ISRAEL  
DEACONESS MEDICAL CENTER FOR  
FISCAL YEAR ENDING  
NOVEMBER 30, 1999**



**JANET REHNQUIST**  
Inspector General

**OCTOBER 2001**  
**A-01-01-01500**

# ***Office of Inspector General***

<http://www.hhs.gov/oig/>

---

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

## ***Office of Audit Services***

The OIG's Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations in order to reduce waste, abuse, and mismanagement and to promote economy and efficiency throughout the Department.

## ***Office of Evaluation and Inspections***

The OIG's Office of Evaluation and Inspections (OEI) conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the Department, the Congress, and the public. The findings and recommendations contained in the inspections reports generate rapid, accurate, and up-to-date information on the efficiency, vulnerability, and effectiveness of departmental programs.

## ***Office of Investigations***

The OIG's Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil monetary penalties. The OI also oversees State Medicaid fraud control units, which investigate and prosecute fraud and patient abuse in the Medicaid program.

## ***Office of Counsel to the Inspector General***

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support in OIG's internal operations. The OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within the Department. The OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops model compliance plans, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.

## **EXECUTIVE SUMMARY**

### **BACKGROUND**

The goal of the General Clinical Research Centers (GCRC) program, which is administered by the National Institutes of Health (NIH), is to facilitate clinical patient-oriented research that will lead to an improvement in the health and welfare of the nation's population. To achieve this goal, the GCRC program provides a clinical infrastructure to investigators who receive their primary research funding from other components of NIH.

The GCRC's are funded as either a discrete center or on a per diem basis. The expected cost of research patient days, nursing, dietary services and other fixed expenses (space costs) are funded in the grant award for a discrete unit. When a discrete GCRC is utilized for non-research patients, the grant is reimbursed by the hospital by means of a credit to the grant. With a per diem unit, only the expected cost of research days is provided in the award and the hospital is reimbursed for the research days actually used. The method chosen depends on cost-effectiveness, unit size, and institutional constraints, and is determined by negotiations between the grantee institution and the GCRC Program.

The Beth Israel Deaconess Medical Center's (BIDMC) GCRC was established in 1964. In Grant Year 1999, NIH awarded BIDMC \$2,832,020 for its GCRC program. The BIDMC GCRC, originally funded in FY 1999 under the discrete method, spans the 8<sup>th</sup> floors of the Gryzmish and Feldberg Buildings. The center consists of an inpatient and an outpatient area, which are physically one contiguous unit.

### **OBJECTIVE**

The objective of our audit was to determine whether the BIDMC had adequate internal controls to ensure the GCRC was utilized in accordance with NIH guidelines and the activity was accurately reported.

### **SUMMARY OF FINDINGS**

The BIDMC needs to improve its system of controls to ensure the GCRC is utilized in accordance with NIH guidelines. During grant year 1999, the GCRC did not have a sufficient level of research utilization and credit days to justify being funded as a discrete unit. In this respect, the BIDMC GCRC inpatient space was utilized only 40.6% for research while the outpatient space was utilized only 37.2% for research. This occurred because the BIDMC did not ensure that estimated patient activity levels were achieved and that grant costs were offset by service credits. Therefore, the GCRC was not operated in the most cost effective manner. It was determined that the GCRC would have been funded approximately \$232,131 less in FY 1999, and \$972,663 less in FY 2001, if the inpatient unit had been funded on a per diem basis, rather than the discrete method.

## RECOMMENDATIONS

We recommend that BI:

- Annually conduct an analysis to determine the most appropriate means of funding the GCRC and work with the NIH to determine the most efficient and effective means for funding the GCRC. Possible options may include 1) funding the center on a discrete basis, with less funded space, salaries, and other costs; 2) funding the center as a smaller discrete unit with additional funding in the form of per diem; and 3) funding the center on a per diem basis for the inpatient unit and a discrete basis for the outpatient unit.
- Ensure that its applications for GCRC funding contain reasonable and accurate estimates of GCRC research activity as well as potential non-research activity.

Subsequent to the initiation of our audit, the NIH informed the BIDMC GCRC that the NIH staff has re-evaluated the BIDMC's discrete budget for FY 2001. As a result, the NIH requested the BIDMC to submit a revised inpatient budget on a per diem basis, which results in a total FY 2001 budget of \$2,728,132 (rather than the proposed discrete budget of \$3,700,795). Alternatively, the NIH noted that the BIDMC may submit a revised budget for a fully discrete center as long as the budget is within \$100,000 of the NIH's proposed per diem budget of \$2,728,132.

### **Auditee Comments and OAS Response**

In its written response to our draft report (See APPENDIX), the BIDMC accepts our figures reported for inpatient and outpatient research activity. In addition, the BIDMC has been working closely with the NIH to assure a cost-effective operation of the GCRC while striving to increase the research effort. However, the BIDMC did not believe that our representation of their overall research utilization was accurate. In this respect, the BIDMC officials stated that the GCRC was open for only 336 days or 2,352 bed days, rather than reported days of 2,401. In addition, the BIDMC officials noted that basing outpatient research utilization on a seven-day work week is not appropriate considering that most outpatient research activity occurs Monday through Friday.

We have made changes, where appropriate, to our final report to address the BIDMC's concerns. In this respect, we revised our calculations of the research utilization percentage to reflect that the GCRC inpatient unit was open for 336 days and the outpatient unit is available only five days per week. This results in research utilization of 40.6% of available inpatient bed days and 37.2% of available outpatient hours (rather than the 37.2% inpatient unit research utilization and 26% outpatient unit research utilization noted in our Draft Report). The BIDMC's response is summarized in the body of our report and attached as an APPENDIX.

## TABLE OF CONTENTS

	<b>Page</b>
<b>INTRODUCTION</b>	<b>1</b>
<b>BACKGROUND</b>	<b>1</b>
<b>OBJECTIVE</b>	<b>2</b>
<b>SCOPE</b>	<b>2</b>
<b>FINDINGS AND RECOMMENDATIONS</b>	<b>4</b>
<b>THE GCRC WAS NOT UTILIZED SUFFICIENTLY FOR RESEARCH</b>	<b>4</b>
<b>Inpatient Utilization</b>	<b>4</b>
<b>Outpatient Utilization</b>	<b>5</b>
<b>BIDMC RESPONSE TO DRAFT REPORT</b>	<b>7</b>
<b>APPENDIX</b>	

## INTRODUCTION

### BACKGROUND

The National Institutes of Health's (NIH) General Clinical Research Centers (GCRC) program encompasses approximately 75 GCRCs located at major medical institutions throughout the United States. These GCRCs provide the infrastructure that allows medical investigators to conduct safe, state-of-the-art, patient-oriented research. The NIH's National Center for Research Resources (NCRR) administers the GCRC program. The goal of the GCRC program is to facilitate clinical patient-oriented research that will lead to an improvement in the health and welfare of the nation's population. The GCRC at Beth Israel Deaconess Medical Center (BIDMC) was established in 1964. In the Grant Year 1999, NIH awarded the BIDMC \$2,832,020 for its GCRC program.

#### *Categories of Patients*

According to NIH guidelines, each patient admitted to a GCRC shall be assigned to one of four categories. *Category A* is for patients who are solely research related. *Category B* is for research patients who also require hospitalization or outpatient studies for diagnosis or treatment according to established standards of care. *Category C* is for patients who are not research subjects and are in the GCRC solely for medical purposes. *Category D* is for research patients on industry initiated projects designed by for-profit organizations. A patient on the GCRC at midnight is considered an inpatient while all others are considered outpatients.

#### *GCRC Funding*

The NIH guidelines for the GCRC program describes the GCRC funding methods as follows: "...There are two general means for funding of GCRCs, the *Discrete Method* and the *Per Diem Method*. The method chosen depends on cost-effectiveness, unit size, and institutional constraints, and is determined by negotiations between the grantee institution and the GCRC Program..."

The expected cost of research patient days, nursing, dietary services and other fixed expenses (space costs) are funded in the grant award for a discrete unit. When a discrete GCRC is utilized for non-research patients, the grant is reimbursed by the hospital by means of a credit to the grant. With a per diem unit, only the expected cost of research days is provided in the award and the hospital is reimbursed for the research days actually used. Payment for each day is based on an average per diem rate for research patients, adjusted for items funded directly by the grant. There are no credits under the per diem method, nor are routine costs awarded.

The Department of Health and Human Services Division of Cost Allocation (DCA) determines the routine costs for a discrete center, as well as the patient care rates to be used for a per diem center. This patient care rate is also the credit offset rate for discrete centers. The GCRC grant funds pay for research costs. They are not intended to pay for established routine patient medical care during the course of research.

### ***The Beth Israel Deaconess Medical Center GCRC***

The Beth Israel Deaconess Medical Center GCRC<sup>1</sup>, funded under the discrete method for FY 1999, consists of an inpatient and outpatient unit. The center spans the 8<sup>th</sup> floors of the Gryzmish and Feldberg Buildings.

- *Inpatient Unit* – consists of eight beds, located in two double and four single rooms. One room is configured for sleep studies and two rooms are wired for remote EEG recording with video monitoring equipment. The nurses' station consists of work space for physicians, nurses, and study personnel. A computerized nurse call system provides specific information for the nurses and assures rapid response to subjects or patients in need of medical or research attention. This unit also includes a medication room, locker room, conference/eating area, computer room, mini kitchen, sample processing laboratory and an anthropometry station. This unit is open seven days a week for 48 weeks a year.
- *Outpatient Unit* – occupies 4,610 square feet of space. This 12 room unit consists of a small interview room, a separate sample processing laboratory, storage room, waiting room, conference room, and a procedure room that has been utilized for exercise studies, clamp procedures, and some general examinations. The unit has two rooms that are configured with two examinations tables and bathrooms, while two rooms have one table. The outpatient unit, which has a total of four beds, is open 7 days a week, 8 hours a day for 48 weeks a year. Over 84% of the outpatient research activity occurs Monday through Friday. Therefore, the unit has a capacity of 7,680 visit hours a year (8 hours X 5 days X 48 weeks X 4 beds).

### **OBJECTIVE**

The objective of our audit was to determine whether the BIDMC had adequate internal controls to ensure the GCRC was utilized in accordance with the NIH guidelines and the activity was accurately reported.

### **SCOPE**

We conducted our audit in accordance with generally accepted government auditing standards. We performed our fieldwork at BIDMC in Boston, Massachusetts from January 2001 through July 2001. The audit covered the period December 1, 1998 through November 30, 1999. In performing our audit, we:

- Held meetings with NCCR to obtain an understanding of GCRC Program Guidelines and to discuss the BIDMC GCRC audit;
- Interviewed BIDMC and GCRC officials to gain an understanding of BIDMC policies and procedures;

---

<sup>1</sup> Hereafter referred to as the GCRC.



- Met with CareGroup Inc. officials to review billing records pertaining to patients seen on the GCRC.
- Met with members of BIDMC's Research Finance Department regarding federal draws made for the grant.
- Reviewed the GCRC FY 1999 Application for Grant Award, Notice of Grant Award, and Annual Report and supporting records.
- Reviewed BIDMC records supporting the GCRC grant's Financial Status Report.

Our audit objective did not include a review of the appropriateness of specific costs charged to the grant. Accordingly, we did not test individual cost transactions.

The BIDMC's response to our draft report is appended to this report and is addressed on pages seven through eight.

## FINDINGS AND RECOMMENDATIONS

The BIDMC needs to improve its system of controls to ensure the GCRC is utilized in accordance with NIH guidelines. Specifically, our audit disclosed that during grant year 1999 the BIDMC did not ensure the GCRC was utilized sufficiently for research. Due to the low level of research utilization, the GCRC may not be cost-effective as currently structured.

### THE GCRC WAS NOT UTILIZED SUFFICIENTLY FOR RESEARCH

During grant year 1999, the GCRC did not have a sufficient level of research utilization and credit days to justify being funded as a discrete unit. In this respect, the BIDMC GCRC inpatient space was utilized only 40.6% for research while the outpatient space was utilized only 37.2% for research. This occurred because the BIDMC did not ensure that estimated patient activity levels were achieved and that grant costs were offset by service credits. Therefore, the GCRC was not operated in the most cost effective manner.

#### Inpatient Utilization

Based on data included in the BI GCRC's 1999 Annual Report, and verified by the OIG, we determined that the funded inpatient space was utilized only 25.3% of the time for inpatient research. The GCRC inpatient space has 8 beds, 7 of which were funded by the GCRC grant. The GCRC is open 7 days a week for 48 weeks. Therefore, the inpatient unit is available for 2,688 bed days per year (2,352 funded by the NIH). The BI GCRC officials noted, however, that outpatients are often seen in the inpatient exam rooms for various reasons including patient safety and comfort, as well as efficiency. The GCRC officials estimate that 1,810 outpatient visits representing 2,879 visit hours took place in inpatient space.

Although we were unable to verify the accuracy of the GCRC official's estimate, we are considering those visits in our assessment of the utilization of the inpatient space. Therefore, in assessing utilization, we estimate that the 2,879 hours is equivalent to 360 inpatient days (2,879 hours divided by an 8 work hour day). After considering the use of inpatient space for outpatient visits, we estimate the research utilization of inpatient space to be 40.6% of funded days and 35.5% of total available days, as shown below.

<b>INPATIENT UTILIZATION</b>					
<b>Category</b>	<b>Days Utilized</b>	<b>Funded Bed Days</b>	<b>% of Funded Days</b>	<b>Total Available Days</b>	<b>% of Available Days</b>
A -Research	487	2,352	20.7%	2688	18.1%
B – Research/Medical	5	2,352	0.2%	2688	0.2%
D – Industry Sponsored	102	2,352	4.3%	2688	3.8%
<b>Total Inpatient Days</b>	<b>594</b>		<b>25.3%</b>		<b>22.1%</b>
Outpatient	<b>360</b>				
<b>Total</b>	<b>954</b>	2,352	<b>40.6%</b>	<b>2688</b>	<b>35.5%</b>

## Outpatient Utilization

The GCRC outpatient space has four exam rooms, which are available for patient visits 8 hours per day for 48 weeks. Considering that over 84% of outpatient research activity occurs Monday through Friday, we will base our assessment of research utilization on a five day week. Therefore, the outpatient space is available for 7,680 visit hours per year (48 weeks X 5 days X 8 hours X 4 beds). In assessing the research utilization of outpatient space, we considered that the BI estimates that only 2,857 of the 5,736 outpatient research hours occurred in outpatient exam rooms (2,879 outpatient visit hours actually occurred in the inpatient space). Therefore, the outpatient rooms were utilized only 37.2% of the available 7,680 visit hours. The following chart summarizes the utilization of the outpatient space

OUTPATIENT UTILIZATION					
Category	Total Outpatient Hours	Available Hours	% of Available Hours	Hours in Outpatient Space	% of Available Hours
A - Research	4,871	7,680	63.4%	2,651	34.5%
D – Industry Sponsored	865	7,680	11.3%	206	2.7%
Total	5,736	7,680	74.7%	2,857	37.2%

***The GCRC did not ensure GCRC costs were offset by the estimated Category C inpatient credits nor did the GCRC ensure estimated research levels were achieved***

The BI’s 1999 application for GCRC funds and corresponding Notice of Grant Award were based on an estimate of 1,037 Category C inpatient non-research days. However, the BIDMC actually utilized only 4 non-research inpatient days, resulting in substantially less credits than anticipated. Further, the actual research activity within the GCRC was substantially less than the estimated 650 research days included in the BIDMC’s application for funds and Notice of Grant Award. Specifically, the GCRC reported only 487 inpatient research days.

***GCRC’s should be operated in a cost-effective manner***

**Criteria -** *The NIH guidelines for the GCRC program describe the GCRC funding methods as follows: “...There are two general means for funding the GCRCs, the Discrete Method and the Per Diem Method. The method chosen depends on cost-effectiveness, unit size, and institutional constraints, and is determined by negotiations between the grantee institution and the GCRC Program...” Therefore, the BI GCRC should ensure that it is operated in a cost-effective manner.*

***The BI GCRC was not operated in the most cost effective manner***

During grant year 1999, the BI GCRC was not operated in the most cost-effective manner. In this respect, the GCRC was awarded, as a discrete center, \$2.8 million. However, during grant year 1999, the GCRC did not have a sufficient level of research utilization and credit days to justify being funded as a discrete unit. In consultation with the NIH, we assumed that, in addition to awarding per diem costs in lieu of routine costs, the NIH would have funded only 6 of 14 nurses and 3 of 5 nutritionists. We determined that the GCRC could have been funded approximately \$232,131 less in 1999 if it had been funded on a per diem basis. The following chart summarizes the cost items affected by changing the inpatient unit from a discrete unit to per diem unit:

<b>OIG's Comparison of Per Diem Budget and Discrete Budget for Grant Year 1999</b>		
	<b>Per Diem</b>	<b>Discrete</b>
Inpatient Space Cost (4,042 square feet @ \$70 per foot)	\$282,940	N/A
Inpatient Per Diem (650 A days X \$821.30)	533,845	N/A
Inpatient Routine Costs	N/A	\$1,321,878
B Ancillaries	N/A	750
Scatter Bed B Days	N/A	3,248
Nursing*	476,649	1,151,901
Dietary*	110,386	183,977
Inpatient Credits	N/A	(1,025,803)
<b>Total</b>	<b>\$1,403,820</b>	<b>\$1,635,951</b>
* The NIH comparison was based on 6 nurses and 3 dieticians under the per diem method and 14.5 nurses and 5 dieticians under the discrete method. The OIG calculation is based on those same assumptions.		

The NIH also determined that funding the GCRC inpatient unit as a per diem unit results in additional cost savings for FY 2001 of approximately \$972,663 in inpatient care costs and nursing and dietary salaries.

**Recommendation:**

We recommend that the BI GCRC officials

- Annually conduct an analysis to determine the most appropriate means of funding the GCRC and work with the NIH to determine the most efficient and effective means for funding the GCRC. Possible options may include 1) funding the center on a discrete basis, with less funded space, salaries, and other costs; 2) funding the center as a smaller discrete unit with additional funding in the form of per diem; and 3) funding the center on a per diem basis for the inpatient unit and a discrete basis for the outpatient unit.
- Ensure that its applications for GCRC funding contain reasonable and accurate estimates of GCRC research activity as well as potential non-research activity.

Prior to initiating audit work at the BIDMC GCRC, we asked officials from the NIH whether they were concerned with the level of utilization and the lack of non-research credits at the BI GCRC. The NIH officials expressed concerns over the low utilization and credits, especially considering the significant disparity between the notice of grant award A and C days and actual activity as disclosed in the Annual Report. We also discussed whether it would be beneficial and cost effective to fund the GCRC on a per diem basis. On June 1, 2001 the NIH informed the BIDMC GCRC that the NIH has re-evaluated the BIDMC's funding methodology and requested the BIDMC to submit a revised inpatient budget on a per diem basis, which results in a total FY 2001 budget of \$2,728,132 (rather than the proposed discrete budget of \$3,700,795). The NIH noted that the BIDMC may submit a revised budget for a fully discrete center as long as the budget is within \$100,000 of the NIH's proposed per diem budget of \$2,728,132.

## **BIDMC RESPONSE TO THE DRAFT REPORT**

The BIDMC's narrative response to our draft report is attached to this report as an appendix. Below we have summarized the BIDMC's comments.

### ***Research Utilization***

#### **BIDMC Response**

The BIDMC accepts the figures reported for the number of inpatient days and outpatient visits. Further, the BIDMC acknowledges that their research utilization has been low and has been working with the NIH to increase research utilization and cost effectiveness. In this respect, the BIDMC stated that there was a significant increase in inpatient research activity in FY 2000 as inpatient A days increased from 487 to 712. However, the BIDMC noted that there was also a significant decrease in outpatient use of the inpatient space. In addition, the BIDMC feels strongly that a change to the per diem funding methodology would jeopardize the GCRC's rebuilding effort.

#### **Additional OIG Comments**

We commend the BIDMC for recognizing the need to increase GCRC research utilization and cost effectiveness. While the BIDMC stated that inpatient research increased significantly from 1999 to 2000, we believe that, based on the data reported by the BIDMC, the overall utilization of the inpatient space has increased only slightly (40.6% in 1999 to 41.7% in 2000). In this respect, as noted in the BIDMC's response to our draft report, reported inpatient research A days increased from 487 in 1999 to 712 in 2000. However, there was a corresponding decrease in the utilization of inpatient beds for outpatient research (1,810 visits in 1999 versus 884 visits in 2000). In addition, reported outpatient visits decreased from 3,774 in 1999 to 2,818 in 2000. While we did not audit the 2000 data, we believe that the research days and visits reported for 2000 demonstrate that research utilization continued to be low after the year under audit.

Regarding the BIDMC's concerns with the per diem methodology, it should be noted that we are not recommending that the GCRC be converted to a per diem center. Instead, we are recommending that other more cost effective means of funding be explored with the NIH.

### ***Utilization Assessment Methodology***

#### **BIDMC Response**

With regard to the OIG's assessment of research utilization, the BIDMC officials do not believe that the OIG's representation of the overall research utilization of the GCRC was accurate. Specifically, the BIDMC officials noted that the GCRC was open for 2,352 funded bed days, rather than the 2,401 as noted in the draft report. In addition, the BIDMC officials stated that the assessment of outpatient utilization should be based on a five day work week, rather than a seven day work week, as most of outpatient activity occurs Monday through Friday.

The BIDMC officials believe that our assessment of research utilization does not take into consideration the complexities of the various protocols and their impact on GCRC resources. These complexities include the varying staffing levels required for each protocol, the timing restrictions (e.g., protocols with fasting requirements) imposed by certain protocols, and time spent by nursing staff planning and implementing each protocol.

#### **Additional OIG Comments**

With regard to the calculations used in our assessment of research utilization, we have revised our draft report to indicate that the inpatient unit is available for research for 2,352 funded bed days and 2,688 total bed days. In addition, we have revised our calculation of the outpatient research utilization to be based on a five-day work week, rather than the seven-day work week used in our draft report. This results in research utilization of 40.6% of available inpatient bed days and 37.2% of available outpatient hours (rather than the 37.2% inpatient unit research utilization and 26% outpatient unit research utilization noted in our Draft Report).

We understand that there are numerous complexities associated with each protocol that should be considered when assessing utilization. However, such complexities are outside the scope of our audit and are to be considered by the NIH when making funding decisions. In assessing utilization for purposes of this audit, our objective was to determine the extent of research utilization in terms of patient days and visits.



# BETH ISRAEL DEACONESS MEDICAL CENTER

A member of CAREGROUP

## Harvard – Thorndike Clinical Research Center

An NIH – funded General Clinical Research Center



A major teaching hospital of Harvard Medical School

**Michael Rosenblatt, MD**  
*Principal Investigator*

**Steven Freedman, MD, PhD**  
*Program Director*

**Alvaro Pascual-Leone, MD, PhD**  
*Associate Program Director*

**Michelle Beck**  
*Administrative Manager*

**Robert A. Parker, ScD**  
*Biostatistician*

**Meredith M. Regan, ScD**  
*Biostatistician*

**Jeanene Fogli, MS, RD**  
*Chief Bionutritionist*

**John Zeind, MS**  
*Core Lab Director*

**Jose Dasilva**  
*Informatics Core Director*

**Mary M. Williams, RN, MS**  
*Nurse Manager*

**Love Nickerson**  
*Administrative Assistant*

October 4, 2001

Michael J. Armstrong  
Regional Inspector General for Audit Services  
Office of Audit Services  
Region I  
John F. Kennedy Federal Building  
Boston, MA 02203

RE: CIN: A-01-01-01500

Dear Mr. Armstrong,

We would like to respond to the preliminary report of the audit done of the General Clinical Research Center of the Beth Israel Deaconess Medical Center (Common Identification Number A-01-01-01500).

### **Inpatient Utilization**

We accept the figures reported for the number of inpatient days. However, as reported in the annual report for grant year 1999, the GCRC was open 336 days. This would mean there were 2,352 funded bed days, not 2,401. Thus the utilization figures are not correct. In addition, there are several factors that should be included in any analysis of the figures.

First, the number of inpatient days and outpatient visits alone do not reflect the appropriate utilization of the GCRC. The complexity of the various protocols directly impacts the utilization of GCRC resources. Space is only one resource. Personnel is another very important resource that must be factored into utilization. For example, an inpatient study that involves drawing blood samples every 10 minutes for 24 hours utilizes resources quite differently than an inpatient observational study. Yet, both yield one day each on the census. An accurate accounting of the cost-effective use of GCRC resources must include an analysis of nursing hours per protocol day.

Next, it should be noted that inpatient activity is not evenly spread over a 24-hour period. The most personnel-intensive activity usually takes place between 8AM and 8 PM. Staffing levels are adjusted accordingly in order to maintain cost-effective use of personnel as well as to meet the needs of the protocols.

RECEIVED  
OCT 23 PM 1:26  
REGION I

The description of the use of inpatient beds for outpatient studies accurately reflects the activity that occurred that year. However, it should also be understood that outpatient activity is not evenly spread over an 8-hour period. Many outpatient studies require the subject to be fasting. Therefore, early morning hours are more heavily utilized. The majority of outpatient visits take place between 8 AM and 12 noon. Based on this, perhaps a more appropriate calculation would be to divide the total hours by 4 hours rather than 8. In addition, the outpatient utilization of the inpatient space is not spread over 7 days. Some outpatient activity occurs on the weekends, but the majority takes place Monday through Friday.

**Outpatient Utilization**

The number of outpatient visits and the associated hours that took place in the outpatient area are reported correctly. However, the outpatient space is not utilized on the weekends. Therefore the 10,976 available hours that are reported in the audit are incorrect. Although the GCRC has the flexibility to accommodate outpatients on the weekends, these weekend visits would occur on the inpatient unit. Those hours were factored into the outpatient utilization of the inpatient unit. Since the outpatient area is utilized Monday - Friday, there are only 7,840 hours available.

In addition, the reported hours of patient visits only reflect the time that the subject was actually in the unit. It should be emphasized that this does not reflect the time spent by personnel before and after each visit. Examples of additional study related activities include set up of the specific study visit, documentation, sample processing, laboratory follow-up, or communication with research team. Some or all of these activities are necessary for every visit. Often the activities associated with a study visit take longer than the actual visit. Independent of the visit, considerable time is spent by the nursing staff planning and implementing each protocol. Any calculation of staffing needs for a per diem unit must factor in these additional hours.

As noted above, complexity of the protocols and nursing hours per visit should be considered in any cost analysis. Next, the utilization percentages assume that the work is spread evenly over 8 hours. However, due to the fasting requirements of most outpatient protocols, many visits occur before 12 noon. Thus, the morning hours are much more heavily utilized than the afternoon.

**Increased Utilization**

The audit reflected activity in the grant year 1999. It should be recognized that in the subsequent grant year 2000, there was a noticeable increase in the inpatient census. Inpatient "A" days increased by over 50% from 487 to 712. In addition, there were 53 "D" days. There were 2818 outpatient visits (2430 "A" and 388 "D"). Due to the increase of inpatient census, there was a corresponding decrease in utilization of inpatient beds for outpatient activity. Of the 2818 outpatient visits, 884 visits took place on the inpatient unit. Those 884 visits reflect a total of 1728 hours (1134 "A" hours and 594 "D" hours). Using the same rationale used in the audit, those hours (divided by 8) reflect 216 equivalent inpatient admissions (142 "A" and 74 "D").

The adjusted inpatient admissions and the percent utilization for grant year 2000 are represented in the table below:

<b>Category</b>	<b>Days Utilized</b>	<b>Actual Days Open</b>	<b>Funded Bed Days</b>	<b>% of Funded Days</b>
<b>A</b>	<b>854 (712+142)</b>	<b>336</b>	<b>2352</b>	<b>36.3</b>
<b>D</b>	<b>127 (53+74)</b>	<b>336</b>	<b>2352</b>	<b>5.4</b>
	<b>981</b>			<b>41.7</b>



Final figures are not available for grant year 2001. However the inpatient census has shown a steady increase over the past 10 months and the inpatient census (not adjusted for outpatient utilization of inpatient beds) has averaged 39.5% for the past 5 months.

**Conclusion**

We are in a period of rebuilding the research activity of the GCRC. Over the past several years, utilization of the GCRC and the performance of patient oriented research in general have been hampered by the changes in health care and increased clinical responsibilities of physicians. In addition, for approximately the past two years we have had an interim Program Director. In part through new commitments to clinical research at BIDMC and also through the designation of Steven Freedman, MD as Program Director, our GCRC is being more utilized and remains the centerpiece of patient oriented research at BIDMC. We have been working closely with GCRC officials at NIH to assure a cost-effective operation of the BIDMC GCRC while allowing us the opportunity to grow our research effort. The institution is recruiting new investigators and GCRC administration has been actively involved with the chiefs of all departments to increase GCRC utilization. We feel strongly that a change to per diem status at this time would jeopardize our rebuilding effort. NIH requested that we submit a budget within \$100,000 of \$2,721,550 (not \$2,728,132 as stated in the audit report) in order to remain discrete. We submitted a budget for grant year 2001 requesting \$2,716,528 in direct costs and were awarded a discrete budget of \$2,705,955. In addition, we have just submitted a discrete budget for 2002 of \$2,718,301 in direct costs.

Sincerely yours,

A handwritten signature in black ink, appearing to read "S. D. Freedman". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Steven D. Freedman, MD,  
Program Director