DEC 06 2001

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

CIN: A-01-01-01501

Dr. Henry J. Binder, M.D.
Professor of Medicine
Director, General Clinical Research Center
Yale New Haven Hospital – East Pavilion
P.O. Box 208076
New Haven, CT 06520-8076

Dear Dr. Binder:

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 Yale University's Adult General Clinical Research Center for Grant Year 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 104-23l), 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-01-01-01501 in all correspondence relating to this report.

Sincerely yours,

Michael J Armstrong

Michael J. Armstrong
Regional Inspector General
for Audit Services

Enclosures – as stated

Direct Reply to HHS Action Official:
Chief, Special Reviews Branch
Office of Acquisition Management and Policy
National Institutes of Health
6100 Executive Blvd. – Room 6B05
Rockville, Maryland **20892**

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

AUDIT OF YALE UNIVERSITY'S ADULT GENERAL CLINICAL RESEARCH CENTER FOR GRANT YEAR 1999

JANET REHNQUIST
Inspector General

DECEMBER 2001
A-01-01-01501

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.

In Grant Year 1999, the NIH awarded Yale $3,142,647 for its Adult GCRC program. The GCRC, funded under the discrete method, consisted of patient exam rooms, 7 patient beds, a nurses station, administrative offices, a kitchen, and processing labs. While GCRC's may have separate inpatient and outpatient units, the Yale University Adult GCRC utilizes the same space for both inpatient and outpatient activity. During our period of audit (FY 1999), the GCRC was located on the 5th floor of the Hunter Building. However, the GCRC has since relocated to the 10th floor of the Yale New Haven Hospital.

OBJECTIVE

The objective of our audit was to determine whether the Yale University Adult GCRC 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 GCRC needs to improve its system of controls to ensure the GCRC is utilized in accordance with NIH guidelines. Our audit disclosed that during grant year 1999 the Yale University did not ensure the discrete GCRC was fully utilized 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 discrete GCRC was utilized only 60% for research. This occurred because the Yale University did not ensure that estimated patient activity levels were achieved and the grant costs were offset by service credits. Therefore, the GCRC was not operated in the most cost effective manner. The NIH advised us that the Yale GCRC would have been funded $444,615 less in FY 1999 if it were funded on the per diem basis. Therefore, unless research utilization increases, we believe the per diem method should be considered as an option to fund the GCRC.

Without increased research utilization, we question the continued use of the discrete funding methodology. For example, in FY 2002 the per diem methodology results in approximately $600,000 less costs than the discrete methodology.

RECOMMENDATIONS

We recommend that the Yale University:

- Ensure its applications for GCRC funding contain reasonable and accurate estimates of GCRC research activity as well as potential non-research activity.

- Annually conduct an analysis to determine the most appropriate means of funding the GCRC and working 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; and 2) funding the center as a smaller discrete unit with additional funding in the form of per diem.

Auditee Comments and OAS Response

In their written response to our draft report (See APPENDIX), the Yale GCRC officials did not agree with the OAS' conclusions that the GCRC was operated at an overall utilization of 60.3% nor did they agree that funding the GCRC as a per diem unit would result in substantial cost savings. The GCRC officials stated that the assessment of utilization should be based on the number of days actually funded in the grant award and should also include the activities of the scatter beds at the Yale Psychiatric Institute. This analysis results in a research utilization of 81%. With regard to cost savings attributable to funding the GCRC on the per diem basis, the Yale GCRC officials do not agree that the GCRC could function effectively with the reduced staffing levels identified in the report.

We have made changes, where appropriate, to our final report to address the Yale GCRC's concerns. In this respect, we clarified our assessment of research utilization to note that we based our analysis on the number of available beds within the discrete unit (without considering scatter beds) multiplied by the number of days the GCRC is open, rather than the number of research days as a percentage of research days awarded.

The Yale GCRC officials also expressed concerns with our estimate of cost savings attributable to converting the GCRC to a per diem unit. It should be noted that we did not recommend that the GCRC be converted to a per diem unit. Instead, we present the per diem method as an option to be considered to increase cost effectiveness, given the current level of research activity. As required by NIH guidelines, the GCRC officials and the NIH should consider the cost effectiveness of GCRC operations when deciding which funding methodology to utilize. Our estimate was based on our discussions with the NIH concerning the possibility of increasing cost effectiveness by converting operations from discrete to per diem. Therefore, our analysis is intended to show the funding differences between the discrete and per diem methods, with a given level of research activity.

TABLE OF CONTENTS

INTRODUCTION 1

BACKGROUND 1

OBJECTIVE 2

SCOPE 2

FINDINGS AND RECOMENDATIONS 3

YALE GCRC RESPONSE TO DRAFT REPORT 5

APPENDIX

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 Yale University Adult GCRC was established in 1960. In the Grant Year of 1999, NIH awarded Yale $3,142,647 for their 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 describe 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, however, these funds are not intended to pay for established routine patient medical care during the course of research.

The Yale University Adult GCRC

The Yale University Adult GCRC[1], funded under the discrete method, consisted of an inpatient and outpatient unit on the 5th floor of the Hunter Building. During our period of audit (FY 1999), the GCRC consisted of a seven-bed unit for both inpatients and outpatients. The unit was open for 292 days during FY 1999, resulting in 2,044 available research bed days (292 days times 7 research beds).

OBJECTIVE

The objective of our audit was to determine whether the GCRC 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 Yale University in New Haven, Connecticut from March 2001 through July 2001. The audit covered the period December 1, 1998 through November 30, 1999. In performing our audit, we:

- Held meetings with the NIH National Center for Research Resources (NCRR) to obtain an understanding of GCRC Program Guidelines and to discuss the Yale University GCRC;

- Interviewed Yale University and GCRC officials to gain an understanding of Yale and GCRC policies and procedures;

- Met with Yale New Haven Hospital billing and admission officials to review billing and admission records pertaining to patients seen on the GCRC.

- Met with Yale Grants and Contracts officials 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 Yale University 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. In addition, we limited our assessment of utilization to the discrete portion (seven funded beds) of the GCRC.

[1] Hereafter referred to as the GCRC.

FINDINGS AND RECOMMENDATIONS

The Yale Adult GCRC 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 Yale University did not ensure the discrete GCRC was fully utilized for research. Due to the low level of research utilization, the GCRC may not be cost-effective as currently structured.

The GCRC was not fully utilized 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 discrete GCRC was utilized only 60% for research. This occurred because the Yale University did not ensure that estimated patient activity levels were achieved and that grant costs were offset by service credits. Therefore, the discrete GCRC was not operated in the most cost effective manner.

Inpatient / Outpatient Utilization

Based on data included in the GCRC's 1999 Annual Report and verified by the OIG, we determined the funded space was utilized only 60% of available time for research. The GCRC has 7 beds and was open for 292 days. Therefore, the unit is available 2,044 days for research (7 beds X 292 days). The GCRC's 1999 application for GCRC funds and corresponding Notice of Grant Award were based on an estimate of 850 Category A inpatient research days and 80 Category B inpatient research days. However, the actual reported activity within the GCRC was substantially less. Specifically, we determined the GCRC reported 628 inpatient research days (420 A days, 196 B days, and 12 D days). Thus, the GCRC was utilized only 31% for inpatient research (628 research days divided by 2,044 available days). However, since GCRC officials noted that outpatients were seen in the same space as inpatients, outpatient activity must be considered.

We determined that reported outpatient research visits took place over 4,851 hours[2]. We are considering this activity in our assessment of the utilization of the inpatient space. Therefore, in assessing the utilization, we estimate that the 4,851 hours is equivalent to 606 outpatient days (4,851 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 / outpatient space to be 60% of funded bed days, as shown below.

Inpatient and Outpatient Research Utilization			
Category	**Days Reported**	**Available Bed Days**	**% of Available Days**
A – Research	420	2,044	20.5%
B – Research and Medical	196	2,044	9.5%
D – Industry sponsored research	12	2,044	0.5%
Total Inpatient Days	**628**		**30.7%**
Outpatient Research	**606**		
Total Research Activity	**1,234**	**2,044**	**60.3%**

[2] The GCRC staff informed us that these outpatient visit hours do not include indirect time. We provided this information to the NIH for their use and consideration.

GCRC's should be operated in a cost-effective manner

> *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… and the GCRC Program…"*

The Yale Adult GCRC was not operated in the most cost effective manner

We met with NIH officials to discuss our concerns regarding GCRC utilization and the GCRC's funding methodology. The NIH officials agreed utilization was low and determined the GCRC could have been funded approximately $444,615 less in FY 1999 had it been funded on the per diem basis, as shown below:

NIH's Comparison of Per Diem budget and Discrete Budget – FY 1999		
	Per Diem	Discrete
Inpatient Space Cost (4977 square feet @ $28 per foot	$ 139,356	$ 0
Inpatient Per Diem (750 A days X $672.68)	504,510	0
Inpatient Routine Costs	0	645,390
Nursing	189,497	852,812
Bionutrition Salaries	84,460	178,309
Service Patient Credits	0	100 B Days x 672.68 = (67,268) 50 C Days x 672.68 = (33,634)
Subtotal	$ 917,823	$1,527,609
Outpatient Space (1548 square feet @ $28 per foot)	43,344	0
Nursing	161,657	0
Service Patient Credits	0	20 B Visits x 22.08 = (442) 350 D Visits x 22.08 = (7,728)
Subtotal	$ 205,001	($8,170)
Grand Total	**$1,122,824**	**$1,567,439**

Without increased research utilization, we question the use of the discrete funding methodology and believe the per diem method should be considered as an option to fund the GCRC. For example, the NIH advised us that in FY 2002 the per diem methodology results in approximately $600,000 less costs than the discrete methodology. However, it should be noted the NIH based its calculations on the GCRC 750 Category A inpatient days even though the centers inpatient activity has historically been much lower. In this respect, reported inpatient A days dropped to 516 in 2000.

Recommendations:

We recommend that the Yale University Adult GCRC Officials:

- ✓ Ensure that its applications for GCRC funding contain reasonable and accurate estimates of GCRC research activity as well as potential non-research activity.

- ✓ 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 smaller discrete unit with additional funding in the form of per diem; and 3) funding the center on a per diem basis.

YALE RESPONSE TO DRAFT REPORT AND ADDITIONAL OIG COMMENTS

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

In its written response to our draft report, the Yale GCRC did not agree with various conclusions supporting our recommendations. Specifically, the Yale officials do not believe our calculation of research utilization is accurate nor do they agree with our analysis of the impact of converting the GCRC from a discrete unit to a per diem unit.

Research Utilization

Yale Response

The Yale GCRC officials stated that our conclusion that the GCRC was utilized only 60.3% of the time for research does not reflect three factors: 1) the funded bed days listed as 2,044 is incorrect because the GCRC was only funded 750 bed days by the NIH; 2) the possibility of greater utilization was limited by the award of 11.2 FTE nursing positions; and 3) research utilization did not reflect the activity of scatter beds at the Yale Psychiatric Institute. The Yale officials stated that the actual utilization rate, after considering those three factors, was 81%.

Additional OIG Comments

We acknowledge the Yale officials statement that the GCRC was utilized over 81% of research days actually funded. However, we believe our analysis presents a more accurate and useful depiction of the utilization of GCRC space and resources. In this respect, the purpose of our assessment of utilization was to determine the extent to which available space was utilized while the Yale officials' analysis merely shows how close the GCRC came to utilizing all of its funded bed days. With respect to the inclusion of scatter beds in the calculation of research utilization, we did not include scatter beds in our assessment as they are not part of the discrete unit. We revised our report to note that we limited the assessment of utilization to the seven discrete beds with the GCRC.

Impact of Converting to the Per Diem Funding Methodology

Yale Response

The Yale officials did not agree with our calculation of the cost savings attributable to converting the GCRC to a per diem unit. Specifically, the GCRC officials do not agree with our conclusion that the GCRC would have been funded $444,613 less in FY 1999 if it were funded on the per diem basis (The GCRC officials did not address our determination that the cost savings would be over $600,000 in FY 2002). The GCRC officials noted that the reduced nursing and bionutrionist staffing levels under the per diem method would not be sufficient to provide the appropriate services to GCRC clients.

Additional OAS Comments

We acknowledge that our analysis does not consider the logistical problems Yale would encounter due to reduced staffing levels. However, both the OAS and NIH agree that with low research utilization, it is difficult to justify the funding of a large discrete unit with several nurses and dieticians. In addition, it should be noted that we are not necessarily recommending that the Yale GCRC be converted to a per diem unit. Rather, we are recommending that the Yale GCRC work with the NIH to determine the most appropriate means of funding, as required by NIH guidelines. The per diem methodology is simply one option to consider.

The estimate of cost savings due to converting to the per diem funding methodology was based on our discussions with the NIH concerning the possibility of increasing cost effectiveness by converting operations from discrete to per diem. During our audit, we advised the NIH that we were concerned about the low level of research utilization within the discrete GCRC. We requested the NIH to provide us with an analysis identifying how funding would be impacted if the GCRC were funded on the per diem basis, given its level of research activity. The NIH advised us that, given the research activity levels and the lack of credits for C patients, it would reduce funding in the areas of space and salaries for nursing and nutrition if the GCRC were funded under the per diem method. Therefore, our analysis is intended to show the funding differences between the discrete and per diem methods, with a given level of research activity.

Yale University

General Clinical Research Center
School of Medicine
YNHH-East Pavilion
P.O. Box 208076
New Haven, CT 06520-8076

November 19, 2001

CIN: A-01-01-01501

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

Dear Mr. Armstrong:

I have received the copy of the U.S. Department of Health Human Services (HHS), Office of Inspector General, Office of Audit Services' (OAS) draft report entitled "Audit of Yale University Adult General Clinical Research Center (GCRC), for Grant Year 1999". I am writing to provide comments relative to the validity of the facts and reasonableness of the recommendations presented.

Audit Report Comment #1: The GCRC should ensure that its applications for GCRC funding contain reasonable and accurate estimates of GCRC research activity as well as non-research activity.

The Audit Report concluded that in 1999 the GCRC operated at an overall utilization rate of 60.3%. I believe that this percentage, shown in the Table entitled **Inpatient and Outpatient Research Utilization** on page 3 of the report, does not reflect three important factors. A) The Funded Bed Days listed as 2,044 in this Table is incorrect in that it reflects the number of beds on the GCRC multiplied by the number of days the GCRC was open, not the 750 bed-days available for research that were actually funded by the NCRR. B) The possibility of substantially greater utilization was limited by the award of 11.2 FTE nursing positions for both inpatient and outpatient activities. (See below for historical basis for the award of this limited number of nursing FTE positions.) C) Research utilization did not reflect the activities of the scatter beds at the Yale Psychiatric Institute (YPI). During the period covered by the 1999 Annual Report 250 Scatter Bed Days were requested and awarded and 209 Scatter Bed Days were used. In the Table below that is entitled **Modified Inpatient and Outpatient Research Utilization** I have

provided information that I feel indicates a more accurate utilization rate of 81% of funded bed days.

Modified Inpatient and Outpatient Research Utilization*				
Inpatient Category (A, B, D and Scatterbeds)	Funded Bed Days Per Audit Report	Days Reported Per Audit Report	Total Days Requested	Days Reported Per YSM Annual Report
A - Research	*	420	750	420
B - Research and Medical	*	196	100	196
D – Industry Sponsored Research	*	12	0	12
Scatterbeds		0	250	209
Total Inpatient Days		628	1100	837
Outpatient Research		606	671	606
Total Research Activity	2044	1234	1771	1443
Percent Utilization		60.3%		81%

*Full census assumed 7 beds x the number of days that the Unit was open (292) in 1999. The initial audit report converted outpatient visits to days based on the actual time involved with each visit including time spent by RN's preparing for a visit.

Audit Report Comment # 2: The GCRC should work with the NIH to determine the most efficient and effective means for funding the GCRC. The funding methodology analysis for year 36 (12/98-11/99) shows that there could be significant cost savings in the areas of nursing and bio-nutrition should the methodology change.

The audit report assumes that funding of the GCRC's inpatient activity as a per diem unit would have resulted in substantial cost savings ($444,613) in the grant year 1999 as a result of reduced needs for both nursing and bionutrition. I do not believe that this assumption is correct for the following reasons.

The Audit analysis suggests that had the Yale GCRC been funded as a per diem Unit that one bionutritionist would have been sufficient to provide meals for the Unit. The Audit analysis did not provide documentation of the estimated number of meal preparations for one FTE but I believe that the calculation must have been based only on inpatient utilization of services and not the full complement of inpatient and outpatient services actually provided.

During the grant year 1999, the Yale New Haven Hospital central kitchen distributed all regular diet trays for inpatient and outpatient studies. The Yale GCRC prepared only special meals (2950) requiring specialized nutrient calculations, product specifications, and menu development. The vast majority of special meal preparation was for outpatients who either came to the GCRC to consume their meals or were given their special meals to take home. One bionutritionist could not have accommodated shifts for a 7 day per week operation to accommodate this load nor could the Yale New Haven Hospital kitchen have prepared these meals. The latter have neither the space nor facilities to support the preparation of necessary meals weighed for metabolic balance and for storage of products purchased only for research studies.

If the Yale GCRC were funded as a per diem unit, Category A inpatients would be hospitalized on a nursing unit with non-GCRC patients. It is extremely doubtful that floor/staff nurses could provide the significant care required for GCRC patients. Difficulties with the Hospital's need to assign beds based on a priority of care, the inability to provide controlled environments, and the use of per-diem and casual nursing staff without any prior research experience or training would also impact on the ability to successfully perform research studies. To complete most, if not all, GCRC protocols it would still be necessary for GCRC inpatients to have "procedure nurses" available at all times when sample collections or any timed activity was required. For example, it is unlikely that floor/staff nurses could successfully perform a protocol that requires blood drawing every two hours through the night. The complexity of the studies performed on GCRC studies requires nurses with special skills and knowledge essential to the successful outcome of the research and the safe and ethical care of research subjects. In addition, the increased nursing acuity of non-GCRC patients and their level of illness (especially today) is such that ill patients take precedent over research subjects.

The draft Audit Report suggests that 3 FTEs could have provided care to GCRC inpatients and 2 FTEs to outpatients. My staff made an assessment of the nursing requirement on the ten most active GCRC protocols that together comprised 62% of total GCRC activity in 1999. In these studies 12,718 RN-hours were required. Working a 40-hour workweek, six procedure nurses would have been needed to provide the appropriate level of service for this activity. Extrapolating to include all inpatient protocols we confirmed the need for 6,000 RN-hours requiring 4 additional inpatient nurses.

I believe that the only costs saving that would have accrued as a result of institutional per diem funding would have been a reduction in the routine costs associated with the actual space required for the seven in-patient beds. All of the other space on the newly renovated GCRC that includes outpatient rooms, special procedure rooms, the Bionutrition, Processing Laboratory, administrative offices, Informatics Core including Biostatistics would have remained.

The GCRC today continues to be constrained by limitations in its nursing personnel. The present GCRC nursing budget does not permit full staffing of the Unit and must close for two weekends each month. As a result, it is extremely difficult to study patients that require more than twelve days of hospitalization. For some time, investigators have not developed such protocols as they are aware that the GCRC must close two weekends per month. This predicament was a result of the previous arrangement that had been mandated by NCRR to reduce nursing costs in which the

GCRC and an inpatient Dermatology Unit had a "mixed" nursing staff that permitted considerable cost savings. Unfortunately, when managed care required the closing of the Dermatology Unit, the GCRC was left to staff a unit on a full-time basis with a limited nursing staff of 11.2 FTEs that is not sufficient to provide seven day staffing.

We are anxious to increase the number of protocols and patients/subjects that utilize GCRC resources and believe that our move to new space within the Hospital in the past year will help us achieve this goal. Nonetheless, I would emphasize that increasing the number of protocols cannot be undertaken without a sufficient cadre of professional personnel.

Sincerely yours,

Henry J. Binder, M.D.
Professor of Medicine
Director, General Clinical Research Center

Cc: D. Kessler, M.D.
GCRC Principal Investigator
YSM Dean

G. Shulman, M.D., Ph.D.
Professor of Medicine
Director Designate