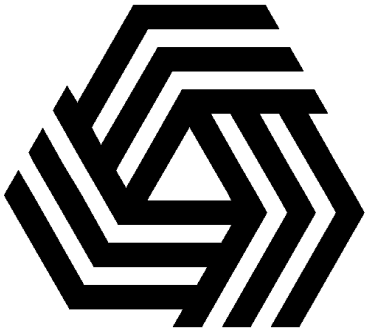

National Center for Research Resources
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Clinical Research

Guidelines for the General Clinical Research Centers Program (M01)

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GUIDELINES FOR THE GENERAL CLINICAL RESEARCH CENTERS PROGRAM of the National Center for Research Resources, National Institutes of Health

I. PURPOSE

The goal of the General Clinical Research Centers (GCRCs) Program is to provide clinical research infrastructure for medical scientists who conduct patient-oriented research. The GCRCs can be used by investigators who are supported by the National Institutes of Health (NIH) and investigators who are supported by funds provided by other federal, state and local agencies, and the private sector. The GCRCs are appropriate sites for pilot studies that may lead to future NIH support, but are not intended to be the sole source of research support for extended studies. The clinical research infrastructure supported by the GCRCs may include inpatient and outpatient facilities, core or other resource laboratories that perform non-routine, sophisticated analyses and procedures, computerized database management and bioinformatics centers, and the necessary support personnel, such as research nurses, research bionutritionists, administrative managers, informatics core managers, biostatisticians, and others. The investigations carried out in the GCRCs can include studies of normal and abnormal human physiology and studies of the cause, prevention, progression, control and cure of diseases that afflict individuals of all ages and ethnic backgrounds. Collaborations between basic and clinical scientists are encouraged. The GCRCs also provide a unique environment for mentored training of health professionals in issues related to clinical, patient-oriented research. Resources are provided to translate basic scientific discoveries into new diagnostic and therapeutic methods that improve the health care of all U.S. citizens. Academic institutions are encouraged to assign the GCRCs a central, leadership role for all of their patient-oriented research.

The GCRC Program has been assigned the number 93.333 in the Catalog of Federal Domestic Assistance.

II. NATURE OF A GENERAL CLINICAL RESEARCH CENTER

Medical institutions supported with funds obtained from public, private non-profit organizations, or governmental agencies are eligible for GCRC Program support. Most grantee institutions of the GCRC Program are affiliated with medical schools but institutions of higher learning that are devoted to medical research may also apply. Inpatient and outpatient areas of the GCRC must be located in facilities either accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or federally certified to accept Medicare and/or Medicaid reimbursement.

The essential feature that is common to all GCRCs is the broad range of patient-oriented scientific inquiry. Investigators from all medical specialities and from basic sciences are encouraged to design and perform interdisciplinary, collaborative research. Because of the general nature of the GCRCs, no single group of investigators or categoric research area may dominate the utilization

of the GCRC or use more than one third of the GCRC resources, except for AIDS studies.

Because each GCRC is designed to support the investigator-initiated, peer-reviewed, clinical research projects within the institution, the configuration and available resources of the respective GCRC vary according to the research needs of the investigators. Consequently, either the inpatient or the outpatient activities may predominate in a GCRC. Likewise, the types of research activities, diseases studied, populations enrolled and ages served reflect the types of supporting grants, all of which must adhere to the NIH policies regarding inclusion of women, minorities and children. The priorities of the research to be performed at each GCRC are determined by the local GCRC Advisory Committee (GAC). This committee also anticipates future needs for clinical research within the institution and proposes new initiatives.

The GCRC Program allows flexibility in the design, accessibility, and scope of research. This facilitates rapid initiation of new and novel protocols and pilot studies. The GCRC Program provides financial support for the components essential to clinical research: operating expenditures, hospitalization and ancillary laboratory costs, and salaries of key personnel including nurses, research bionutritionists, administrators, core laboratory directors, biostatisticians and computer personnel. Funds for renovation and equipment may also be provided.

A. Inpatient Area:

The inpatient facility of a GCRC is usually located within a physically discrete unit that contains inpatient rooms and research beds. It may also include administrative offices, a laboratory, research bionutrition area, computerized data analysis facility, and other supporting services required to perform high quality clinical research. Ideally, the GCRC is in close proximity to other established patient care units. Supported inpatient research may also include studies conducted in other "scatter-bed" areas such as psychiatric wards or intensive care units.

B. Outpatient Area:

Clinical research that involves outpatients frequently complements or provides an alternative to inpatient investigations. This type of research may be performed in one of several locations on the inpatient unit, in a separate dedicated GCRC outpatient area, in a regular hospital outpatient clinic or in another discrete area assigned for GCRC use on a *pro rata* basis. Staffing and space allocations depend on the scope and complexity of the outpatient investigations.

C. Core Laboratories:

The primary functions of a Core Laboratory are to provide sophisticated support to ongoing GCRC protocols and to develop or validate new methods for this purpose. In addition, the

laboratories may provide clinical research training for investigators, fellows, students, and technicians.

Core Laboratory requirements vary widely. Some GCRCs may not need a full Core Laboratory, rather only a small sample-processing area. In general, however, laboratory equipment, supplies, and personnel are supported through the GCRC grant when it has been documented that they will serve several investigative groups. Under special circumstances, a test for a single group of investigators may be supported if it is within the Core Laboratory's capabilities and is critical to conduct an investigation of high scientific merit and program relevance.

In general, routine tests, such as blood chemistries, hematologic determinations and urinalyses, that are available in the hospital's clinical chemistry laboratories or in another Medicare-approved clinical chemistry laboratory are not performed in the GCRC Core Laboratory, but rather supported through ancillary funds. However, such tests may be performed in the GCRC Core Laboratory when this is critically important for timeliness, when an extreme degree of accuracy is needed, or if patient safety is at stake. Whenever possible, cost sharing of Core Laboratory functions should be sought from the investigators.

Core Laboratories include laboratories performing radioimmunoassays, but may also include, depending on the needs of the GCRC, specialized laboratories for, for example, exercise physiology and body composition, mass spectroscopy, magnetic resonance imaging, ultrasound, positron emission tomography, tissue culture, cell biology, molecular genetic analyses of DNA obtained from patient material, and/or cell and gene therapy.

Core Laboratories are encouraged to share their specialized expertise with other GCRCs. Records of such services and collaborations should be kept, as they may be helpful in justifying continued support of the laboratory. See below (Section IV-G-11) regarding Program Income.

The GAC is responsible for reviewing the Core and other resource Laboratories to assure that the activities are serving the research needs of a wide array of investigators, that laboratory tests are not routine, and that priorities are set for the use of the Laboratory when concurrent demands exceed the Laboratory's capacity. In all cases, NIH-supported investigations are to be given the highest priority.

D. Informatics Core:

A clinical investigator must be able to publish his/her scientific findings. This requires that data be (1) collected accurately, (2) monitored appropriately, (3) secured, (4) managed effectively, and (5) accessible for analysis and reporting. The mission of the Informatics Core is to provide the information infrastructure necessary to accomplish this.

For a GCRC to be successful and efficient, information flow between the GCRC Cores must be both timely and accurate. The Informatics Core interacts with the other GCRC Cores, integrating the information needs of the Center.

The Informatics Core should facilitate the secure and confidential sharing of scientific data between research centers.

The Informatics Core should provide leadership in exploring and implementing new technologies to stimulate and promote clinical research.

The Informatics Core provides education and training in the use of information technologies and research data management to the GCRC staff and research teams.

The requirements of the Informatics Core will depend both on the specific needs of the GCRC and the existing institutional resources. In all cases, each Informatics Core should have a file server to comply with current and anticipated NCRR bioinformatics goals to communicate within and between GCRCs. The file server should meet standards for the secure storage, archiving, management, and analysis of protocol data. A network should be in place to facilitate GCRC operations and investigations associated with all GAC approved studies. The Informatics Core should insure that GCRC network facilities are accessible to all GCRC Core components and promote the adherence to data management standards. The Informatics Core should also provide or facilitate ongoing training and education in the use of its resources.

The GAC is responsible for reviewing the Informatics Core activities to ensure that the research needs of a wide array of investigators are being served. The GAC will prioritize the use of the Informatics Core resources when concurrent demands exceed capacity, with NIH-supported investigations being given the highest priority. Initiatives which might have a substantive impact on the Informatics Core should be presented to the GAC for review and approval.

E. Bionutrition Research Area:

A GCRC Bionutrition Research Area is supported to provide the controlled dietary regimens for either GCRC inpatient or outpatient studies. However, not all GCRCs require a Bionutrition Research Area. A cost effective means to provide meals should be used, outsourcing when appropriate. The Bionutrition Research Area may function as an important resource to train medical and paramedical personnel.

F. Principal Investigator:

The Principal Investigator (PI) of a GCRC derives no salary support from the grant and is an individual whose authority transcends departmental lines--for example, the Dean of the medical school. Requests for an exception will be reviewed on a case-by-case basis. The PI has the ultimate responsibility for the administration and operation of the GCRC, and is the person with

whom the NIH communicates on broad institutional matters relating to the GCRC grant. The GCRC Program Director, National Center for Research Resources (NCRR), should be notified immediately in writing when a change in PI is planned. The letter should include the curriculum vitae of the proposed individual. The PI appoints the Program Director (PD) and members of the GAC (see Section II-G) and is responsible for the development of the GCRC as an institutional resource. Should the PI determine that a new PD is needed for the GCRC, it is his/her responsibility to seek approval from the GCRC Program Director, NCRR, for such a change. This request should be accompanied by a current curriculum vitae, and information regarding existing sources of peer-reviewed research support. All requests are to be cosigned by the authorized institutional business official and the PI.

G. Institutional GCRC Advisory Committee:

The GAC usually consists of 8 to 12 members, appointed by the PI, on a rotating basis. This Committee is responsible to the PI. It should be composed of a cross-section of the faculty members who are familiar with the broad elements of the GCRC research activities. The GAC shall not be chaired by the PD or Associate/Assistant PD. Individuals in Program Directorship positions shall not be voting members of the GAC. The GAC supervises and reviews the operations of the GCRC, its Core Laboratories, and Informatics Core; sets general policies; delineates common needs of the GCRC investigators; establishes admission policies; and evaluates projects for GCRC use. Studies on the GCRC must have GAC approval prior to initiation, except when temporary approval has been given by the PD or his/her designee and the Institutional Review Board (IRB) for urgent studies created by an unexpected opportunity to study unusual research patients.

The GAC should prioritize projects for GCRC use in order to assist the PD in allocating resources. In all cases, NIH-funded clinical research must be given preference. The GAC is responsible for assuring implementation of existing NIH policy on the inclusion of women, minorities, and children as study subjects. The GAC must also designate for each protocol, the category of inpatient research days and outpatient visits as Category A, B, or D (see Sections II-N and IV-G). For appropriate classification of industry-related projects, the GAC must review copies of the research agreement between the investigator and industry, an itemized budget, and other relevant correspondence, detailing the drug, or other therapeutics or devices supplied.

The GAC should periodically review GCRC operations to ensure that GCRC resources are used for the most scientifically justified and relevant projects. It should also encourage junior faculty members to perform clinical research and assist them in applying appropriate concepts and methods. Meetings of the full GAC should be held at least quarterly, and detailed records must be kept. The minutes of the GAC meetings are examined at the site visit when the GCRC grant application is reviewed. The GAC may form subcommittees to carry out some of its functions. These may include the review of biostatistical design of projects, ethical concerns, and the assignment of priority scores based on scientific merit as well as their need for GCRC resources.

The GAC should include a biostatistician both to assist with the review of project design and to optimize subsequent data analyses.

H. Institutional Review Board for Human Research:

All research projects conducted in the GCRC must be reviewed and approved by the IRB to ensure protection of the rights and welfare of research subjects (see 45 Code of Federal Regulations 46). 45CFR46.110 allows expedited review for certain kinds of research. The Office for Protection from Research Risks, NIH, is responsible for the oversight and implementation of 45CFR46. The composition of the IRB and its attendance records and minutes are examined at the site visit when the GCRC grant application is reviewed. All research projects must be approved by the IRB as well as by the GAC. The IRB is also responsible for the implementation of the NIH policies of inclusion of women, minorities and children in all protocols, where appropriate. The activities of the Data Safety and Monitoring Boards also need to be coordinated through the IRB. If the IRB becomes aware of information that would bear on the safety of a GCRC protocol, it is incumbent upon the IRB to re-review that protocol. Likewise, it is the investigator's duty to notify the IRB of any new information that is considered to be relevant to the safety or efficacy of a GCRC protocol for which he/she is responsible. Documentation of IRB approval of protocols, as well as copies of currently approved consent forms, should be maintained in the GCRC administrative files.

I. Grant-Supported Personnel:

The personnel positions which may be supported by GCRC grants are listed below (see Section IV-B for allowable costs). The number of positions supported in each category depends upon the size and complexity of the GCRC as recommended by the NIH peer review system and set by program priorities. No portion of the salary of the PI may be supported by the GCRC grant.

1. Program Directorship: The PD is a senior physician-investigator and a medically licensed, full-time member of the institution's faculty who derives a portion of his or her salary from the GCRC grant for administration of the GCRC. The PD reports to the PI, and works closely with the GAC. Furthermore, the PD should be a productive clinical investigator who holds independent peer-reviewed research support and has active GCRC-based protocols. In the event that a PD loses all independent peer-reviewed research support, up to two years will be allowed for submission of grant applications and subsequent funding. If the PD still does not have independent peer-reviewed research support by the end of that time, the PI must nominate a new PD. "Independent peer-reviewed research support" as described herein, is not limited to NIH support; other sources of peer-reviewed support will satisfy this requirement.

The PD's activities include supervision of GCRC nursing, bionutrition, paramedical, and administrative staffs, and the organization and operation of the Core Laboratories, Informatics Core, and Bionutrition Research area. The PD must be familiar with all research projects conducted on the GCRC, and assure that the research is carried out as approved by the local IRB.

Support for a PD from the GCRC grant is ordinarily limited to a maximum of 0.50 full time equivalent (FTE). Requests for an exception will be reviewed on a case-by-case basis. The PD should provide a focus through which clinical research skills are taught to medical students, house staff, fellows, Clinical Associate Physicians (CAPs), and other junior faculty members. In addition, the PD is expected to be an expert clinician who can command respect and instill the highest standards of clinical research and medical care in the GCRC staff and investigators.

Most GCRCs will require additional administrative oversight from Associate and/or Assistant Directors. The Associate PD should be a licensed physician and full-time faculty member who is currently conducting research on the GCRC and holds peer-reviewed research support. Support provided to an Associate PD from the GCRC grant may reach a maximum of 0.50 FTE, as long as the individual is either a principal investigator or co-investigator on a NIH grant or other significant source of peer-reviewed funding. If an Associate or Assistant PD loses all peer-reviewed grant support, that individual will be allowed two years to become a principal investigator or co-investigator of a peer-reviewed grant. If the individual is unsuccessful at the end of that time, either a new Associate PD shall be appointed, or the level of support from the GCRC grant reduced to 0.25 FTE or less. An Associate PD usually assists the PD in the administrative oversight of the Center; this includes the quality of inpatient and outpatient medical care, nursing, paramedical, Core Laboratory, and research bionutrition staffs. The Associate PD may supervise an inpatient or outpatient satellite facility apart from the main GCRC and commonly assists the PD in teaching clinical research methods to medical students, house staff, fellows, and faculty. The total level of Program Directorship reflects the level of GCRC research activity and its complexity.

2. Administrative Support: The Administrative Manager is a skilled specialist, responsible to the PD for the day-to-day management of GCRC administration, fiscal matters and records of GCRC activities. He or she maintains the statistical and financial data needed by the grantee institution and the NCRR Office of Grants Management and for Annual Reports to the GCRC Program, NCRR. In the interest of GCRC efficiency, the PD may delegate some administrative authority in non-scientific and non-health care delivery matters to the Administrative Manager.

If warranted by the size of the GCRC, a full- or part-time Administrative Assistant may be supported to perform duties related to GCRC operations such as maintaining GAC meeting records and consent forms. Administrative Assistants are not supported from GCRC funds to prepare renewal applications or to provide support for developing scientific publications for the Program Director or other investigators. In general, Facilities and Administrative (F&A) costs provided to an institution by the grant support clerical assistants who prepare grant applications and manuscripts for publication.

3. Core Laboratory:

a. Core Laboratory Director: A Core Laboratory Director may supervise the Core Laboratory operations if the scope and sophistication of the laboratory procedures justify such a position; otherwise, the laboratory is supervised by the PD or Associate PD, often through a senior laboratory technician. A Core Laboratory Director is an individual with an advanced degree who may also provide training in sophisticated laboratory techniques to GCRC-based investigators, their laboratory personnel, junior faculty or fellows. This position usually requires only a small fraction of an FTE. A larger portion of a Core Laboratory Director's time may be required in the initial establishment of complex laboratory procedures, with a smaller fraction of the Laboratory Director's time being required for routine laboratory activities. When there are multiple Core Laboratories with different functions (e.g., radioimmunoassay core, mass spectrometry core), the GCRC grant may support a fraction of an FTE for the Director of each.

b. Core Laboratory Personnel: The Core Laboratory staff must possess the expertise needed to provide reliable and accurate analyses required by GCRC research activities.

c. Quality Control: The GAC must assure that there are appropriate quality control programs in compliance with existing Federal and local requirements, such as the Clinical Laboratory Improvement Amendments where applicable.

4. Nursing:

a. Head Nurse/Nurse Manager: The Head Nurse/Nurse Manager is responsible for the administrative organization of the GCRC nursing staff (cost effective staff distribution), training, patient care delivery, and interaction with investigators to assure that research projects are carried out as approved by the IRB and the GAC. The Head Nurse/Nurse Manager should have a Bachelor of Science degree in Nursing, must be licensed within the state and have staff privileges within the hospital wherein the GCRC is located. GCRCs which have many complex projects or a large number of outpatient research visits may require an Associate Head Nurse/Nurse Manager to assist in providing the research patient care needs. That individual should have an educational background and nursing experience comparable to that of the Head Nurse/Nurse Manager of the GCRC.

b. Nursing Staff: The GCRC nursing staff should be trained to make complex research observations and perform precise collections of specimens, while providing exemplary patient care. The staff should be assigned exclusively to the GCRC and not be assigned to duties outside of the GCRC. For the same reason, nurses who are not regular members of the GCRC staff should be assigned to the GCRC only in emergencies. The professional level and number of nursing personnel required for a GCRC are determined by the size of the unit, the number of research inpatient days and outpatient visits, and the complexity of the research and medical care performed on the GCRC. All nurses must be licensed and have staff privileges either at the

hospital in which the GCRC is located or satellite or scatter bed unit. Except for the smallest centers, support of either a full-time or part-time Ward Clerk, Unit Manager or Unit Secretary is appropriate.

5. Bionutrition Research:

a. <u>Bionutrition Research Manager</u>: Those GCRCs that have metabolic or other protocols that demand sophisticated nutritional support may justify a position for a Bionutrition Research Manager. This person should have a Bachelor's degree and be a registered dietitian, R.D.. The Bionutrition Research Manager oversees the GCRC dietary staff and works closely with both the nursing staff and physician-investigators. Up to 1.0 FTE may be supported.

b. <u>Nutrition Staff</u>: The preparation of controlled diets for research subjects requires special skills and meticulous attention to detail. To provide the research subjects and investigators with optimal service the bionutrition staff should be assigned exclusively to the GCRC. The staff number and professional level are determined by the nature of the research, the number of research patients requiring dietary control, and the complexity of the nutritional studies.

6. Informatics Core: The Informatics Core Manager is responsible for its overall operation. Due to the evolving nature of information technology, the Informatics Core Manager should work closely with the PD to ensure that current technologies are employed to meet the GCRC's goals. The Informatics Core Manager should be competent to assist in the organization and analysis of research data and be familiar with the broad array of basic methods of data analyses. He/She must ensure that the tasks necessary to achieve the goals of the Informatics Core are implemented, including:

1. Work with GCRC investigators to design and develop methodologies that meet accepted standards for research data management.

2. Instruct GCRC staff and investigators in the use of Informatics Core resources.

3. Facilitate the dissemination of information within and outside of the GCRC.

4. Work with the biostatistical staff on GCRC-approved protocols.

5. Ensure the proper operation and maintenance of GCRC computer hardware and software.

6. Develop and maintain a strategic plan for the Informatics Core.

The minimum qualifications for the Informatics Core Manager include a Master's degree or formal training in research methods and 2 years of experience in application development or computer/network management.

Additional Informatics Core staff may be employed when needed to fulfill the goals of the Informatics Core**.**

7. Biostatistician: The GCRC Biostatistician should hold a doctoral degree in biostatistics or statistics, or have comparable training and experience. The GCRC Biostatistician should have experience in the planning, design and evaluation of clinical research. The GCRC Biostatistician reviews all protocols and is a voting member of the GAC. The GCRC Biostatistician consults, and may collaborate, with investigators on study design, implementation, analysis, interpretation and dissemination of results. He/She should develop new statistical methods as needed for specific projects and train clinical researchers in the principles of study design and analysis. Total support of up to 1.0 FTE will be provided to a GCRC for this individual or other biostatisticians working under his/her direction.

8. Clinical Associate Physician Program: Supplement II of these guidelines outline the CAP Program in support of the career development of investigators who have made a commitment to patient-oriented research.

The former Minority Clinical Associate Physician (MCAP) and the Clinical Research Scholars (CRS) Programs are now incorporated in the CAP Program. The new CAP guidelines supersede all previous CAP, MCAP, and CRS guidelines.

9. Medical and Dental Students: The GCRC may rebudget, with institutional prior approval, up to $10,000 annually from nonrestricted categories for salaries of medical or dental students who participate with faculty investigators in research on clinical projects in the GCRC. Funds for this purpose may also be requested in the GCRC competing renewal applications, outlining the method of selection, projected roles in research activities and plans to follow the careers of the students. Student salaries should be consistent with institutional standards for similar appointments, up to the maximum allowed by the NIH National Research Service Act (NRSA) Short-Term Research Training (T35) Grants.

The financial support provided to these students should be prorated based on the salary schedule for predoctoral NRSA trainees. Salaries may be supplemented in keeping with NRSA guidelines, and further may be used in conjunction with the Department of Education Work-Study Program.

The purpose of this support is to both facilitate the progress of GCRC protocols and to provide clinical research experience for students who are interested in pursuing a career in biomedical research. It is expected that the selection of the recipients will be based on a competitive review by the GAC. Information about the research activities of students supported from these funds is required in the GCRC Annual Reports.

J. Provisions for Medical Care:

1. General: Research subjects, whether inpatients or outpatients must receive optimal medical care. A physician with appropriate expertise and admitting privileges should be substantively involved in any research protocol involving GCRC resources and human research subjects. Each investigator is responsible for the care of patients admitted under his or her research protocols, either personally or through designated co-investigators, fellows or residents. The PD or his/her designee must be familiar with the nature of all admissions and conduct daily rounds to assure that appropriate patient care is being provided on the GCRC. An Associate or Assistant PD may assist with the oversight of this responsibility. Arrangements for emergency and night care must be formalized. House officer coverage is desirable.

2. Intercurrent Illnesses: The appropriate disposition of a patient who develops an illness during the course of study depends on the severity of the illness and its relationship to the research. The patient may be treated on the GCRC when the illness is unrelated to the research but is anticipated to be of short duration. If the intercurrent illness requires termination of the studies or their interruption for a substantial period of time, other arrangements for the patient's care should be made.

K. Training and Career Development:

The training of health professionals in the methods of clinical investigation should be an integral part of the research effort on every GCRC. The GCRC should serve as the institutional focus for training in clinical research methodology, bioethics, biostatistics, clinical trial design, epidemiological studies and basic laboratory methods. Formal courses may be set up for this goal and include NRSA fellows and trainees as well as CAPs and junior faculty.

Regular rotation on the GCRC by research fellows, house officers, and medical, nursing, and dietary students is encouraged. Because GCRCs are expected to represent models of excellence in current clinical research techniques, they may also be used for other instructional purposes, including programs of continuing education for practicing physicians, nurses and dietitians. These activities, along with the use of the Core Laboratory for training in research methodology, are the responsibility of the PD but may be delegated to an Associate or Assistant PD.

Each student or postdoctoral fellow who participates in research on a GCRC must have a qualified mentor identified in GCRC records. This supervisor, typically the principal investigator of the protocol on which the trainee is working, is responsible for the medical and scientific quality of the work performed by the trainee.

L. Annual Reports:

Each grantee institution is required to submit an Annual Report of scientific progress and an annual Financial Status Report (FSR) within 90 days after completion of the grant year. These

reports are reviewed by NIH staff and are used for planning and evaluation. Through these reports, the NIH staff is kept apprised of current research activities and accomplishments at each GCRC for Congressional reports and budget justifications and for other reports.

M. Credit on Publications:

All publications that result from utilization of any of the GCRC resources (e.g., inpatient area, outpatient area, Core Laboratory, Informatics Core) should cite the grant as a contributing source of support and indicate the GCRC grant number, including the prefix "M01RR." Publications crediting the GCRC grant should be approved by all listed co-authors. Each GCRC must maintain a current and complete bibliography of GCRC-related publications for inclusion in its Annual Report, and for program-wide inquiries of scientific accomplishments. It is recommended that GCRC scientific and administrative records be retained for at least five years.

N. Industry-Sponsored Research:

GCRCs are sometimes used for projects funded in whole or in part by for-profit organizations. Investigator-initiated projects which are partially supported by such an organization through a grant of unrestricted funds or by a donation of drugs or devices may be pursued on the GCRC in the usual manner, subject to the usual IRB and GAC review and approval. Funds from the proprietary organization which are budgeted for research patient care must be credited to the patient care category of the GCRC grant if the GCRC is used. Copies of the agreement with the drug company or other source must be maintained in the GCRC's administrative files. In addition, copies of other relevant correspondence, along with the Food and Drug Administration (FDA) letter assigning an Investigational New Drug (IND) number and approval for initiation of studies with any relevant experimental drug or device, are to be maintained in the GCRC's research project files.

Those projects which are designed by for-profit organizations will be considered industry initiated. That organization is expected to pay for the use of the GCRC facilities at the same rates that it would pay for any other hospital beds and ancillary charges at that institution. This can be accomplished by classifying research subjects in such projects as Category D patients (see Section IV-G). All Category D patient charges are to be paid to the hospital from funds provided by the commercial organization. In some cases, investigators may add additional research aims to the project. In that case, the GAC ascertains the relative resource needs to be contributed by the company, GCRC, and investigator's resources. All industry-initiated projects must be approved for use of the GCRC by the GAC. Industry-initiated projects should constitute only a small portion of total GCRC activity. In some cases, a commercial organization may provide clinical research funds for an investigator-initiated study. If investigator-initiated, the research project is appropriately classified as Category A or Category B rather than Category D. The funds provided by industry are to be credited to the patient care category of the GCRC grant.

The determination of whether a research project is industry-initiated or investigator-initiated is to be made by the GAC, using the above general principles after reviewing the appropriate documents. Deliberations are to be documented in the minutes of the GAC. Investigators who are receiving industry support for projects conducted on the GCRC must be free to publish or distribute data from such studies without restriction.

III. PHYSICAL FACILITIES

A. General:

The design of a GCRC must facilitate the proper conduct of patient-oriented investigations. Usually the GCRC is geographically discrete and adjacent to a routine hospital patient care area/unit. It should include adequate space that enables research operations to be performed in an optimal manner. While regular patient traffic routes should not traverse the GCRC, the GCRC should be located close to other patient care areas if possible, so that clinical services and emergency care are readily available. The GCRC must be in a facility accredited by the JCAHO or federally certified to accept Medicare or Medicaid reimbursement. All renovations of GCRCs financed by NIH grant funds must meet applicable federal guidelines. (Guidelines for Construction and Equipment of Hospital and Medical Facilities.)

GCRC relocation, within the current hospital or to a new hospital, or changes in the current space which differ from those recommended in the last peer review must be reviewed and approved by the GCRC Program, NCRR, prior to initiating the modifications. Detailed drawings of the floor plan along with a list indicating the use and number of square feet for each room, a narrative justification, and an estimate of cost for the revised GCRC site should be co-signed by either the PD or PI and the appropriate Business Official and submitted to the GCRC Program, NCRR.

B. Inpatient Area:

Space requirements for the inpatient area are dependent on local codes, JCAHO standards, research needs and federal guidelines. Space should be adequate both for patient comfort and for equipment used in bedside studies. It is preferable that at least half of the research beds are located in private rooms, to accommodate gender or age differences. Rooms that provide controlled environments such as those involving laminar air flow, special monitoring or isolation, may be supported if justified scientifically for patient or staff safety. The nurses' station should be large enough to accommodate the nursing and paramedical staffs. Ideally the office for Head Nurse/Nurse Manager, a doctors' writing area, and a patient lounge, which may also serve as a reception area for outpatient research studies, should be provided. A treatment or procedure room is usually essential for research and patient care procedures. Adequate storage space and utility rooms, in keeping with JCAHO guidelines, must also be provided. Occasionally more than one inpatient facility may be required for a GCRC, such as when large numbers of both pediatric and adult patients are being seen simultaneously.

C. Outpatient Area:

A facility for outpatient research can be located in the GCRC inpatient area or in a unit that is geographically separate from the hospital outpatient department. A contiguous unit could share supporting facilities and paramedical staffs with the inpatient GCRC and is usually more cost-effective and provides greater flexibility for research. Space requirements of the outpatient area depend upon the scope of the outpatient activities. The inpatient reception area, patient lounge, and examining rooms can be utilized if they are of sufficient size. In some cases, patient beds on discrete GCRCs may be used for complex outpatient studies that require a visit lasting several hours. Additional offices and treatment rooms may be necessary. The area should be functionally designed specifically for outpatient studies; a doctor's consultation room may serve two or more examining rooms.

Renovations for ambulatory research operations need not be extensive or costly. Many existing GCRCs can handle outpatient visits with little modification of their physical structure. When the GCRC outpatient research must be carried out in a unit of the hospital outpatient department, efforts should be made to maintain the discrete nature of the outpatient research area with regard to both location and scheduling.

D. Core Laboratory:

Core Laboratory research facilities should be within the boundaries of the GCRC or in a nearby location. A specimen processing area is often an essential part of the GCRC even when no analytical Core Laboratory is required.

E. Bionutrition Research Facility:

A Bionutrition Research area, if justified for the proposed research program, should be located in or near the GCRC. Specially defined and routine diets can usually be served from the same kitchen. The size of the kitchen will depend on the number of subjects who will receive special and routine diets. An office for the Bionutrition Research Manager should be located near the kitchen.

F. Office and Conference Space:

Office space for the PD and the administrative staff should be provided on or near the GCRC. Offices for an Associate PD, Core Laboratory Director, or other personnel are sometimes justified. A conference room is often needed for meetings, research seminars and teaching purposes, especially for large GCRCs.

The Informatics Core should be located in dedicated space on or adjacent to the GCRC. The physical facilities should include an Informatics Core Manager’s office, a user/training room, and a secured room for the file server(s). The computer facilities should be configured for both local

and remote access. Both hardware and software should be the focus of a rational renewal strategy to maintain information technologies that meet the evolving needs of the investigators.

IV. GRANT MANAGEMENT

A. General:

The award and administration of GCRC grant funds are subject to the laws, regulations, and policies indicated in the Notice of Grant Award, the Terms and Conditions therein, and these Guidelines. Awarded funds for patient care costs and nursing and bionutrition salaries and their related fringe benefits may not be transferred to other budget categories without approval from both the GCRC Program Director and the Office of Grants Management, NCRR. Rebudgeting between nonrestricted budget categories must be in compliance with NIH rebudgeting policies. As described below, Category A activities at a GCRC may be commingled with other patient-oriented research activities (such as Categories B and D activities), provided appropriate individual programmatic accounting is maintained. In addition, other patient-oriented research units may be co-located with a GCRC, provided appropriate fiscal accountability exists.

In accordance with NCRR policy, the recurring direct costs (direct costs excluding equipment) requested for the first year of a competitive renewal application cannot exceed the final noncompeting year's budget direct recurring costs budget by more than 20 percent. Where this policy may significantly limit the program scope of the proposed research, the applicant may request a waiver of the 20 percent ceiling. A letter, clearly justifying the request for a waiver must be submitted to the GCRC Program Director, NCRR, well in advance of the application receipt date. The waiver to the ceiling must be approved in writing by the GCRC Program Director, NCRR, before the center's competing renewal application is submitted and accepted.

B. Personnel Costs:

Salaries and wages of personnel may be charged to the grant in proportion to the time which they devote to GCRC activities. Salaries of personnel paid by the GCRC grant must not exceed the salaries of personnel in comparable positions elsewhere within the institution. Fringe benefits, if not included as an F&A cost, are allowable as a direct cost in proportion to the salaries charged to the grant, provided that such payments are made under institutional policies which are formally established and consistently applied. Charges must be in accord with applicable institutional policies and records must be maintained to substantiate these charges. Sabbatical leave salaries for GCRC personnel are not allowable charges to the GCRC grant; however, sabbatical leave costs to the institution may be included in a composite fringe benefit rate or in the institution's F&A cost rate. An appropriate salary may be charged to the GCRC grant for the person performing the duties of the GCRC staff member who is on sabbatical.

C. Equipment:

Fixed or movable equipment for patient, laboratory, dietary, informatics and administrative areas may be purchased with grant funds if necessary for GCRC activities and not otherwise available to the GCRC from within the institution. Equipment not requested in initial, renewal, or supplemental applications may be purchased from unexpended grant funds, as permitted by institutional and *NIH Grants Policy Guidelines*. Requests for such purchases from funds available in patient care categories (including salaries and fringe benefit monies for the research nursing and dietary staffs), accompanied by a detailed justification, must be submitted to the GCRC Program, NCRR, by the PD and co-signed by an authorized Business Official of the institution.

D. Consumable Supplies:

Consumable supplies for the Core Laboratory, Informatics Core, and the GCRC administrative office may be purchased with grant funds provided in the supply budget category. Routine hospital, drug, and raw food supplies are ordinarily provided for within the patient care cost budget categories and are not directly charged to the supply budget category of the grant.

E. Travel:

Domestic travel by the PD and other staff members which will provide direct benefit to the administration of the GCRC may be paid for by the grant. This may include meetings of the Program Directors, Informatics Core Managers, Biostatisticians, Administrative Managers, Nurse Managers, and Research Bionutritionists, and travel of GCRC personnel for consultation with the GCRC Program, NCRR. These travel/meeting costs are specifically indicated on the Notice of Grant Award. Funds for patient travel are not allowable charges to a GCRC grant, but may be reimbursable through other sources.

F. Other:

The Other category usually encompasses miscellaneous services directly related to the GCRC operations, such as software and hardware maintenance and training, equipment maintenance contracts, and duplicating services. Publications such as patient handbooks, annual reports for the lay public, and public information documents, are allowable as publication costs and may be included in the Other category. However, research publication costs (page charges, reprints, etc.) are an individual investigator's expense and are not chargeable to the GCRC grant. Subscriptions to research publications are allowable only if they are of direct relevance to a significant number of GCRC staff members. Membership fees to scientific and professional organizations are not allowable charges to a GCRC grant, nor are payments to research subjects for their participation in any protocols.

G. Patient Care Costs:

l. General: Research patient care costs incurred under GCRC grants must be computed using research patient care rates or amounts established by the regional office of the Department of Health and Human Services (DHHS). Such rates must be used in all requests and claims for research patient care costs. The institution must submit patient care rate proposals annually to the DHHS Regional Office and reply promptly to inquiries from that Office. Inpatient utilization is based on midnight census.

2. Patient Categories: Each patient admitted to the GCRC shall be assigned to one of four categories: Research (Category A), Research Service (Category B), Industry-Initiated (Category D), and Non-Research (Category C). These assignments are to be made prospectively for each research project by the PD and GAC, in consultation with the involved investigator. The GAC evaluation of research projects for GCRC use is to be made exclusively on the basis of the scientific merit of the projects and their need for the GCRC, without regard to the assignment of patients to Category A or B. In all cases, NIH-funded clinical research has the highest priority status.

GCRC grant funds pay for research costs. They are not used to pay for established patient medical care or treatment during the course of research. When Category C and Category D patients are admitted to a GCRC, all costs for their care are charged to the patients or third parties rather than to the grant.

a. <u>Research Patients (Category A)</u>: These are research inpatient days or outpatient visits utilized solely for research purposes. All hospitalization costs associated with Category A research days or visits are the financial responsibility of the grant or the investigator's research funds. Persons who are hospitalized for research purposes only, but whose care is partly supported by non-GCRC funds, (e.g., other grants, industry) may also be classified as Category A. This category includes normal volunteers or control subjects and patients who may participate in research projects that include unproven forms of therapy or diagnostic techniques that may subsequently become standards of medical therapy or diagnosis. Even though a patient may have a third party carrier and have an underlying disease, the GCRC assumes all research costs related to patients in this category.

GCRC grant funds may be used to pay all costs, thereby encompassing the usual care costs, which are part of the research project, as well as research care costs. This financial responsibility is assumed for the entire period of hospitalization, research testing or provided services for patients who would not otherwise have been hospitalized or received such tests or services except for their participation in the research study. Any exceptions should be documented in GCRC administrative records.

These patients may include persons to whom no health advantages may be expected to accrue as a result of the hospitalization. Examples would be persons with genetic or other abnormalities of

interest to the investigator, and those persons who although sick, would not have otherwise been brought to the hospital except for the research studies.

b. Research Service Patients (Category B): This category pertains to patients who require hospitalization or outpatient studies for diagnosis or treatment according to established standards of care. Although these patients also participate in GCRC-based research studies, the cost of established medical care, i.e., non-research care, for Category B patients is not charged to the grant. The patient or third party carrier is responsible for those costs. The institution is responsible for all billings and collections on these patients. A patient care credit, or offset, for each Category B inpatient day or outpatient visit is credited to the patient care category of the grant based on the patient care rate agreement for inpatient days or the rate developed by the GAC for outpatient visits (see Section IV-G-6). The cost of those ancillary services performed solely for research on Category B patients and not related to their routine medical care should be charged to the grant and not appear on the patient's hospital bill which is submitted to either the patient or the insurance carrier. Patients who meet the Category B classification criteria may not be classified as Category A simply because they lack applicable insurance.

c. Industry-Initiated Projects (Category D): This category includes inpatient days or outpatient visits utilized for an industry-initiated study. All charges are paid directly by industry through the responsible GCRC investigator. For each Category D inpatient day, a credit is provided to the patient care category of the grant based on the patient care rate agreement. In addition, the GCRC receives a credit for each outpatient visit and use of any other GCRC resources. The charge for each project is to be developed by the GAC and credited to the patient care category of the GCRC grant (see Section IV-G-6).

d. Non-Research Patients (Category C): Patients who are not participating in a research project may be admitted to the GCRC solely for the purposes of diagnosis or treatment according to established procedures, only when there is space and staffing available on the GCRC. The purpose of Category C inpatient admissions and outpatient visits is to decrease the cost of the operation of a discrete GCRC. As with Category B patients, the hospital is responsible for all billings and collections that involve Category C patients. Because Category C patients are not participating in research projects, no charges for their hospitalization or visits may be made to the grant. The requirements for providing credits to the grant are the same for Category C patients as for Categories B and D patients.

It is essential that the presence of Categories D and C patients not compromise other research activities involving Categories A and B patients on the GCRC. Admission of all Category C patients must therefore be at the discretion of the PD and the GAC. Dialysis patients, post-operative patients, intensive care patients, and other patients who require an extraordinary level of paramedical and nursing effort, should not be admitted as Category C patients.

3. Scatter-bed Inpatient Days:

a. Category A:

i. The cost of occasional, unexpected, temporary use of special facilities, such as an intensive care unit or other off-site area uniquely required to accommodate a research patient, may be charged to the GCRC grant provided that the care is required by the nature of the clinical research or by an illness resulting from the research; the care is provided in a specialized area (intensive care unit, coronary care unit, etc.); the occasional patient remains on the GCRC census under the scatter-bed classification while in the special care unit; and there is no duplication of payment for patient care. The GAC must review and approve this local activity.

ii. If the use of special facilities such as an intensive care unit or other off-site area is to be an established part of a GCRC research project and was not previously peer reviewed, prior written approval from the GCRC Program, NCRR, is required. The request is to be co-signed by the appropriate Business Official.

iii. If the cost of the proposed scatter-bed research activity combined with the support of the original peer-reviewed and recommended configuration of a GCRC exceeds the National Advisory Research Resources Council (NARRC) recommended funding level, then a competitive supplement may be submitted for peer-review of the request (see Part A).

b. Category B: As defined above for Category B inpatients on the unit, Category B scatter-bed patients require hospitalization for diagnosis or treatment according to established standards of care but are also research subjects. These off-site inpatients may require ancillary services solely for research purposes that may be charged to the grant. Scatter-bed B research inpatients with ancillary costs charged to the GCRC grant will be tracked as scatter-bed B days. If a GCRC research nurse is required, the nurse's time is tracked separately as "Scatter-bed Research Nurse Hours" (see below).

c. Category C and Category D: These categories are not classifications used for scatter-bed research days.

4. Scatter-bed Research Nurse Hours:

a. Category A and Category B: A GCRC research nurse may be required to perform the research component of a study on a Category B inpatient hospitalized off-site on an approved scatter-bed research project. Scatter-bed research nurse hours will be tracked by project for nurses who are paid directly by the GCRC grant. The hours tracked will reflect all the requisite time associated for each research project (for example, scheduling, preparation, direct patient research procedures, chart entry). Scatter-bed research nurse hours are entered in the Annual Report for each subproject by patient category (A, B or D). Total scatter-bed research nurse hours for all subprojects combined are computed by the Annual Report Program and

displayed at the end of Section 11 of the Annual Report. The scatter-bed research nurse hours associated with all off-site research inpatients should be recorded. If ancillary costs are not charged to the GCRC grant, no Category B scatter-bed inpatient days are recorded. Off-site "B" research inpatient projects that have no ancillary charges will require only scatter-bed nurse hours to be tracked. Category A scatter-bed days are recorded since either inpatient costs or ancillary costs (or both) are paid by the GCRC grant. Scatter-bed research nurse hours for Category A projects will only count the hours of nurses paid directly by the GCRC grant, not those nurses whose salaries are included in a *per diem* charge.

b. <u>Category D</u>: With the approval of the GAC, a Category D project with patients hospitalized off-site may have a scatter-bed research nurse assist in the study. Scatter-bed research nurse time for an off-site Category D research project should be tracked and appropriate financial credit should be made to the GCRC grant.

5. Outpatient and Research Meal Visits: A GCRC research subject who is not hospitalized at midnight is considered to be an outpatient. Thus, an outpatient visit could be as short as a few minutes or as long as almost 24 hours. The visit may take place on the GCRC unit or at a remote site, as long as it is funded by the GCRC grant and/or involves a GCRC nurse. There is no category called "scatter outpatient visit."

When a research subject is on the unit to eat or pick up a research meal and has no contact with either GCRC nurses or investigators, the interaction is categorized as a research meal visit, not as an outpatient visit. The research meal visits should be tracked and reported in the Nutrition section of the Administrative Narratives in the Annual Progress Report and listed as “research meal visits."

6. Outpatient Visit Credits: Charges for Category D (industry-initiated) visits, Category C visits, and the non-research portion of Category B visits are to be credited to the GCRC grant. This activity must be reflected in the computations on the census page of the Annual Progress Report, and must be included as a credit in the patient care computation pages of the Annual Progress Report.

For each project, an appropriate credit, preferably based on an hourly rate, must be computed. In developing a rate, all components of the GCRC utilized are to be included, i.e., program directorship, administration, research bionutrition, nursing, core laboratory, computer, biostatistical services, space charges, as well as any other appropriate GCRC resource. A rate should be established and approved by the GAC.

7. Changes in Patient Category: A patient's category may change during the hospital stay on the GCRC. For example, a patient may be designated as Category B during the first part of an admission, when the patient would have been hospitalized regardless of research participation, and subsequently as Category A after the completion of standard care because components of the research project have yet to be completed. Similarly, part of a research

subject's hospital stay may be Category D and another portion Category A or B. The categorization is determined prospectively by the GAC.

8. GCRC Funding Methods: 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, NCRR.

a. Discrete Unit Method: With this method, most often used for large or medium-sized GCRCs, the expected cost of all research inpatient days, nursing, dietary services, and other fixed expenses are funded in the grant award. When Research Service (Category B), Industry-Initiated (Category D), or Non-Research (Category C) inpatients are cared for on the GCRC, the grant is reimbursed by the hospital by means of a credit ("offset") to the grant based on the annual DHHS negotiated rate agreement. Category B, C and D patient credits may not be rebudgeted to nonrestricted budget categories by the grantee institution without prior approval from the GCRC Program Director, NCRR.

b. Per Diem Method: With this method, the expected cost of the Research Patient (Category A) inpatient days is provided in the grant award but the hospital is reimbursed only for the Category A days actually used. The payment for each day is based on an average routine per diem rate for Category A patients, adjusted for any items funded directly by the grant, such as some or all of the nursing. When the per diem rate includes hospital-provided nursing, the grant will usually support one or more additional Research Nurses.

c. Discrete vs. Per Diem Comparison: In comparing per diem versus discrete methods of funding, the following should be used as a guide:

	Per Diem	**Discrete**
Space Cost		N/A
Per Diem Cost		N/A
Routine Costs	N/A	
Nursing Salaries (FTEs)		
Bionutrition Salaries (FTEs)		
Service Patient Credits	N/A	

Description of Cost Items:

Space Costs -- On a per diem GCRC, space costs may be requested for administrative offices, laboratory space, computer space, and research bionutrition space. A detailed description of square feet per office/room should be provided. Cost should be based on the number of square feet applicable to these areas which is then calculated by multiplying the square feet by the square foot dollar rate for the hospital.

Per Diem -- The per diem cost is usually the Medicare rate for the hospital. This rate for a per diem center should be the Service Patient Credit rate for a discrete center. The per diem is calculated by applying this rate to the number of Category A days requested.

Routine Costs -- This is the cost for the total inpatient space of the GCRC.

Nursing -- On a per diem GCRC, research nursing salaries for a Nurse Manager and 1 or 2 additional nurses may be paid directly. The number of nurses depends on the level of outpatient activity and the intensity of nursing care required. In unusual circumstances, more than 2-3 nurses may be needed.

Bionutrition Research Salaries -- On a per diem GCRC, the dietary component must be justified based on the need for a bionutrition research component. Normal patient meals should be provided by the central hospital kitchen.

Service Patient Credits -- This is the Medicare rate applied to B, C and D patients on a discrete Center.

Ancillary costs are generally not affected by the method of funding, and thus are not considered in the above.

9. Scatter-bed Reimbursement: Some studies require that patients be cared for in beds not located on the GCRC. These are referred to as scatter-beds. If Category A scatter-bed days have been funded in the award statement, or prior approval has been obtained from the GCRC Program, NCRR, patient care costs will be provided using a negotiated inpatient routine per diem applicable to the area where the patient is housed. Scatter-bed patients often are Category B, in which case the only cost to the grant is for the ancillary costs associated with the research.

10. Ancillaries: All ancillary services provided to Category A patients and those provided to Category B patients which are not required for their routine medical care but are performed solely for research can be supported from GCRC grant funds. Ancillary services are defined as services routinely available through hospital departments for all patients in the hospital. This definition applies even when these services are purchased from sources outside the hospital for reasons of economy or efficiency. Tests needed by individual investigators for their research are not proper charges to the GCRC grant if the tests are not routinely available to all patients in the

hospital. Also, services provided either by the laboratory of a GCRC researcher or by a hospital laboratory or service which is directed by a GCRC researcher (even if that researcher has a contractual arrangement with the hospital to provide these services) may not be charged to the GCRC grant for any project for which that researcher is the principal investigator or a collaborator. Research ancillary charges must be reduced to cost based upon the Negotiated Rate Agreement between the hospital and DHHS.

11. Program Income: Program income is defined as the gross income earned by a grant recipient that is generated directly by an activity supported by the grant or earned as a result of the grant (see 45 CFR 74.2 and 74.24 for additional information). An example of program income is fees resulting from charges made for laboratory tests performed by the GCRC Core Laboratory. An estimate of the amount and source of program income expected to be generated as a result of the GCRC grant award must be included on the Checklist Page of all competing and noncompeting continuation applications. Net program income earned during a budget period must be reported on the long form FSR (except for program income earned as a result of inventions, to which special rules apply). Costs incident to the generation of program income may be deducted from gross income to determine program income, provided these costs have not been charged to the award.

Program Income earned during the project period shall be retained by the GCRC recipient and, in accordance with the terms and conditions of the award, used in the following way:

a. The first $25,000 earned during a budget period is added to funds committed to the project or program, and used to further the objectives of eligible projects or program;

b. Any amount over $25,000 earned during a budget period is to be deducted from the total project or program allowable costs in determining the net allowable costs on which the federal share of costs is based. NCRR may offset a future award by this amount or reauthorize it for expenditure on a future award.

H. Professional Fees:

1. Category A patients: Physicians' fees or other professional services may not be charged to the grant for Category A patients, except when included in the charge for a hospital service to a research patient AND that hospital department providing the service, such as radiology, pathology, and anesthesiology has a contractual agreements with the grantee institution or participating hospital. Administrative approval by the GCRC Program, NCRR, is required prior to implementing payment for those professional fees.

2. Category B patients: Physicians' fees may not be charged to the GCRC grant for Category B patients. However, physicians' fees may be charged directly to Category B patients or third parties. Budgetary records should be maintained to document this process. To avoid apparent or real conflicts of interest, professional fees charged and collected by the hospital on

behalf of GCRC investigators should be deposited directly into divisional or departmental accounts so that no investigator is the direct recipient of patient fees.

I. Consultant Fees:

Consultant fees to physicians are not allowable charges to a GCRC grant.

J. Alterations and Renovations:

Approved renovations of an existing structure to provide facilities for a GCRC (see Physical Facilities section) may be paid by the grant. Funds may not be used for new construction or for completion of "shell space." All renovations of GCRCs financed by NIH grants must meet applicable federal guidelines (*Guidelines for Construction and Equipment of Hospital and Medical Facilities*, latest edition).

K. Facilities and Administrative Costs:

A special or off-campus F&A cost ("modified F&A") rate is normally required for all GCRC grants, since F&A costs such as depreciation, operations and maintenance, housekeeping, and space costs for the GCRC facilities are included in the direct component of patient care costs. Patient care costs also include F&A costs related to hospital-affiliated employees supported as a direct cost by the grant, regardless of the identity of the employer. Therefore, the base used to claim F&A cost must exclude all hospital-affiliated costs (salaries and fringe benefits for nurses, bionutritionists, ward clerks, social worker, etc., and patient care costs).

L. Overall GCRC Funding:

Funding for each GCRC each year is based on prior utilization and productivity and projected total (not just inpatient) patient-oriented research activity. This includes inpatient, scatter-bed, outpatient, nursing, research bionutrition, core laboratory, training, biostatistics, and computer analysis needs.