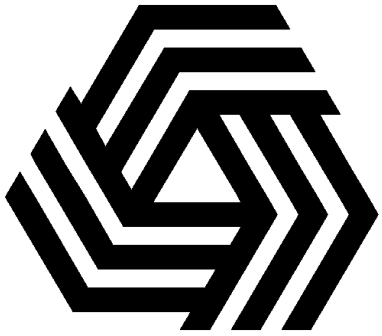

National Center for Research Resources
National Institutes of Health
Department of Health and Human Services

Clinical Research

Guidelines for the General Clinical Research Centers (GCRC) Program

Supplement I: Instructions for Preparing a GCRC Application

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An Administrative Document Issued by the
National Center for Research Resources (NCRR).

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INSTRUCTIONS FOR PREPARING A GCRC APPLICATION

I. ELIGIBILITY FOR GRANT SUPPORT

Medical institutions or governmental agencies are eligible for General Clinical Research Centers (GCRC) Program support. The primary purpose for a GCRC is to provide the clinical research infrastructure to investigators who receive their primary research funding from the other components of the National Institutes of Health (NIH). While most grantee institutions of the GCRC Program are affiliated with medical schools, other institutions devoted to medical research may also apply. Inpatient and outpatient areas of a GCRC must be located in a facility accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), or federally certified to accept Medicare and/or Medicaid reimbursement. GCRCs provide the infrastructure for high quality clinical research for physician-scientists currently funded by the federal agencies, private foundations, and other peer-reviewed sources. The resources of a GCRC may include inpatient and outpatient facilities, specialized personnel, Core Laboratory, and Informatics Core.

II. REVIEW OF APPLICATIONS

Each GCRC application submitted to the NIH is evaluated by three groups--first, by a site visit team composed of members of the GCRC Committee (Initial Review Group) and *ad hoc* consultants; next, by the GCRC Review Committee (National Center for Research Resources (NCRR)); and finally, by the National Advisory Research Resources Council (NARRC), which makes its recommendations to the Director of the NCRR. Criteria for evaluation of a new or competing renewal GCRC application include scientific merit of the proposed research, peer-reviewed research project support for GCRC investigators, program relevance, value as an institutional and regional resource, utilization by several medical disciplines, evidence of collaboration between basic and clinical scientists, availability of a sufficient research patient population, and the prospects for use of the GCRC as a clinical research training facility for medical students, house staff and subspecialty fellows.

New and competing continuation (renewal) applications, using Form PHS 398 are accepted and reviewed according to the following schedule:

Received By	**Project Site Visit**	**GCRC Committe Review**	**Council Review**	**Earliest Possible Funding Date**
October 1	Nov. - Jan.	February	June	July 1
February 1	March - May	June	September	December 1
June 1	July-Sep.	October	February	April 1

Form PHS 398 is available at most institutional offices of sponsored research and from the Office of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, Room 6095, Bethesda, MD 20892-7910; phone: (301) 435-0714; fax: (301) 480-0525; e-mail: GrantsInfo@nih.gov. Forms are also available on the NIH Web site: http://www.nih.gov/grants/funding/phs398/phs398.html.

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.

Applications are recommended by the NARRC for project periods of varying length, up to a maximum of five years. Funding of approved initial or renewal applications depends on the availability of funds to the GCRC Program Director as well as the relative priority of the GCRC as assigned on the basis of the above criteria.

Requests for support for Clinical Associate Physicians (CAPs) award as well as other types of resources above the level previously recommended by the NARRC, should be made by a competing supplemental (Type 3) grant application, using Form PHS 398. Program Directors are encouraged to consult with NCRR's GCRC Program staff before submitting a competing supplemental request. Supplemental requests exceeding $500,000 in direct costs for any year will not be accepted without prior consultation with and approval by the GCRC Program Director, NCRR. The format and review of supplemental grant applications are similar to those of new and renewal grant applications, except that the information to be included (projects, biographical sketches, tables, etc.) need be only the material required to justify support of the items requested in the supplemental application. The deadline receipt dates for supplemental applications are the same as those for new and renewal GCRC applications. Site visits are not usually required for supplemental applications unless they are very large or require additional assessment of GCRC resources.

Competing supplemental applications dealing only with research on acquired immunodeficiency syndrome (AIDS) may be given an expedited review. Such applications should meet the criteria given in the previous paragraph with the following modifications: (1) In order that the application be considered for expedited review, the submission dates are January 2, May 1, and September 1. (2) All projects in the supplemental application must be AIDS-related. And, (3) the application must have approval of the Institutional Review Board (IRB) for all projects at the time of submission and must be so indicated on the first page of the application. If a site visit is involved,

expedited review may not be possible. Program Directors (PDs) are encouraged to consult with NCRR staff before submitting such an AIDS competing supplemental application

SUGGESTED STEPS IN PLANNING A GCRC APPLICATION

A. Examine the Guidelines for the GCRCs.

B. Discuss the need for a GCRC with investigators from different departments at your institution. From these discussions and from meetings with institutional administrators, determine the following:

   1. Number of investigators with peer-reviewed sources of support who will utilize the GCRC for clinical research;

   2. Number and types of investigations that could effectively utilize GCRC resources, with encouragement of multidisciplinary use (resource needs of investigators);

   3. Number and category (A versus B, see below) of research inpatient days and outpatient visits required by the research project;

   4. Biostatistical, Informatics Core, Core Laboratory, bionutrition research and administrative support required;

   5. Optimal location for the GCRC within the institution.

C. Plan a visit to one or more established GCRCs to learn about GCRC administration and scientific oversight.

D. Make a preliminary sketch of the proposed GCRC. If necessary, obtain cost estimates for alterations and renovations.

E. Indicate whether the hospital has a currently effective Department of Health and Human Services' (DHHS) negotiated hospitalization rate agreement for inpatients; if not, determine the basis to be used for calculating patient care costs.

F. Outline a draft proposal and discuss it with the staff of the GCRC Program Director, NCRR.

III. SPECIFIC APPLICATION INSTRUCTIONS

Form PHS 398 should be used for all new and competing GCRC applications and supplemental applications. These specific instructions supplement the instructions attached to Form PHS 398. Follow Form PHS 398 instructions except where they differ from the specific instructions below.

Page limitations specified in Form PHS 398 instructions do not apply to GCRC applications; they have been modified as described below.

Submit a signed, original typewritten application with the Checklist, and three single-sided, unbound, signed photocopies, in one package to: Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1040, Bethesda, MD 20892-7710 or for express/courier service use Bethesda, MD 20817-7710. In addition, send two single-sided copies to: Clinical Research, National Center for Research Resources, 6705 Rockledge Drive, Room 6070, Bethesda, MD 20892-7965; or for express/courier service use Bethesda, MD 20817-7965

When submitting a revised (-A1) application, summarize in an "Introduction" section substantial additions, deletions and changes that have been made in all sections including all projects. Highlight these changes within the text of the "Research Plan" section by appropriate bracketing, indenting, or changing of typography. Do not underline or shade changes. Include any work done since the previous version was submitted. A revised application will be returned if it does not address criticisms in the previous summary statement and/or an "Introduction" is not included and/or substantial revisions are not clearly apparent.

Amended (-A1) applications may be reviewed at a site visit at the applicant institution, or may be reviewed at an “applicant interview.” The NCRR Office of Review will make that decision and will notify the applicant institution, and include the agenda for the applicant interview. -A2 applications will generally not have a site visit. The NIH Policy on Submission of Revised (Amended) Applications which can be found at http://www.nih.gov/grants/policy/amendedapps.htm states that “the National Institutes of Health (NIH) will no longer consider any A3 or higher amendments to an application and, regardless of the number of amendments, the NIH will not accept a revised (amended) application that is submitted later than two years beyond the date of the receipt of the initial, unamended application. The new policy applies to all mechanisms.”

All applications are due on or before the established deadline date. No request for a waiver will be considered prior to receipt of the application, and there is no guarantee that the waiver will be granted by the Center for Scientific Review (CSR). NCRR staff cannot grant a waiver. To request a waiver, include an explanatory letter with the signed, completed application.

Do not send any supplementary or corrective material pertinent to an application after the receipt date without specific solicitation and agreement by the Scientific Review Administrator (SRA) of the GCRC Review Committee or the site visit SRA. There is no guarantee that the reviewers will consider late material.

Pay close attention to type size specifications and limitations outlined on page 10 of the Form PHS 398 Kit.

ITEM 1. TITLE OF PROJECT: General Clinical Research Center

ITEM 2a. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT: No

ITEM 3. See instructions for Form PHS 398.

ITEM 3. a. NAME OF PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR: Name of Principal Investigator. Only the Principal Investigator's name and not the Program Director's name should be entered on this line. If Program Director's name is entered here the review of the application may be unduly delayed. Only one name per application is recognized in the NIH computer system.

ITEM 3. b, c, d, e, f, g, h. See instructions for Form PHS 398.

ITEM 4. See instructions for Form PHS 398. For item 4a, indicate "Yes." For "IRB Approval Date" indicate the date on which IRB approval was completed for all of the projects in the application.

If IRB approval of all protocols in the application is not completed by the time of submission of the application, enter "Pending." A follow-up certification of IRB approval of all protocols in the application must be submitted to the SRA of the GCRC Review Committee, and received within 60 days of the application submission or by the time of the site visit, whichever occurs first.

Any protocols which are not IRB approved at the time of the site visit will not be considered a part of the application, and if a protocol was scheduled to be one of the presented protocols at the site visit but does not have IRB approval at that time, it will not be allowed to be presented. “IRB approval” means full, final IRB approval including IND assignment and approval from FDA if an IND is required. “Provisional” IRB approval is not acceptable.

If a follow-up certification of IRB approval has to be sent to the SRA of the GCRC Review Committee, an appropriately completed and signed Optional Form 310 (available on request from CSR) continues to meet the requirements for certification. In lieu of this preferred form, a letter prepared on organizational letterhead stationery or a revised Face Page is acceptable provided that all of the following required information is included: title of project, application number, name of investigator and institution, Multiple Project Assurance number, date of IRB approval, and appropriate signatures. The Optional Form 310, the organizational letter, or the

revised Face Page with an attachment must contain any changes or modifications required by the IRB and if none, a statement to that effect.

ITEM 5. [If projects include use of vertebrate animals, further information, as described in of the Form PHS 398 Kit, must be provided.] The information in Items 5a and 5b and the signatures on the Face Page fulfill the requirement for verification of IACUC approval. To insure against delays in the review of the application, IACUC review is best completed prior to submission of the application. However, if the IACUC review is unavoidably delayed beyond the submission of the application, enter "pending" at Item 5. A follow-up verification of IACUC approval from an official signing for the applicant organization must then be sent to and received by the SRA of the GCRC Review Committee within 60 days after the receipt date for which the application is submitted. Any modifications in the Research Plan section of the application required by the IACUC must be submitted with the follow-up verification. Occasionally PHS initial review may be scheduled to occur before the end of the 60-day grace period. In these special cases of accelerated review, the follow-up verification will be requested earlier. Otherwise, it is the responsibility of the applicant organization to submit the follow-up verification. The PHS does not guarantee that it will remind the applicant organization or the Principal Investigator/Program Director to provide this missing information. If verification of IACUC approval is not received prior to the scheduled PHS initial review date, the application will be considered incomplete and deferred to the next review cycle.

If a follow-up verification of IACUC approval has to be sent to the SRA of the GCRC Review Committee, an appropriately completed and signed letter, prepared according to the example in the PHS Policy on Humane Care and Use of Laboratory Animals, continues to meet the requirements for verification. In lieu of this preferred method, a revised Face Page is acceptable, provided that all of the following information is included: application number, title of project, name of investigator and institution, Animal Welfare Assurance number, date of IACUC approval, and appropriate signatures. An attached page should contain any changes or modifications required by the IACUC, and if none, a statement to that effect.

ITEM 6. <u>DATES OF PROPOSED PERIOD OF SUPPORT</u>

The entire proposed project period may not exceed five years. Applications can not be funded until the NARRC has completed its review. After the first year or fraction of a year, the annual funding period will begin on December 1. The project period end date of supplemental applications may not extend beyond the funded project period end date of the Center grant. Refer to the most recent Notice of Grant Award.

ITEM 7 through 16. See instructions for Form PHS 398.

DESCRIPTION

Describe the major areas of investigation to be undertaken on the GCRC.

KEY PERSONNEL

Include only the Principal Investigator, Program Director(s) and other professionals (e.g., biostatistician, core laboratory director) for whom salary is requested. Do not include the names of the investigators of the individual projects.

TABLE OF CONTENTS

Structure the application according to the format below. Number pages consecutively from the beginning to the end of the application without ancillary numbering systems. Applications which do not conform to this format may be returned.

PART I. BUDGET

A. Detailed Budget for Initial Budget Period (12 months or less)
B. Budget for Entire Proposed Project Period (up to 5 years)
C. Budgets Pertaining to Consortium/Contractual Arrangements and Budget Justification

PART II. BIOGRAPHICAL SKETCHES: provide an index in alphabetical order, with a page number for each individual. Biographical sketches are to be no more than two pages per individual.

A. Biographical Sketches
B. Other Support

PART III. RESOURCES AND ENVIRONMENT

A. Background and Introductory Statement
B. Organizational Framework
C. Administration
D. Patient Care
E. Training and Career Development
F. Core Laboratories
G. Biostatistical Support
H. Informatics Core
I. Physical Resources and Utilization
J. Other Existing or Planned Resources for Clinical Research

PART IV. RESEARCH PLAN

A. Accomplishments
B. Center Bibliography (for competing renewal applications)
C. Research Projects: listed by project principal investigator in alphabetical order. Provide page index for all research projects at the beginning of Section IV-C, along with title of the proposal and name of protocol principal investigator.

PART V. TABLES

A. Faculty Member Research Participation
B. Training
C. Utilization of the Center, Last Three Years (for competing renewal applications)
D. Principal Users of the Center, Last Three Years (for competing renewal applications)
E. Proposed Scientific Agenda for the Site Visit and Abstract Package

PART VI. SITE VISIT INFORMATION

Pages 4+5
(Form PHS 398)

PART I. BUDGET

A. Detailed Budget for the Initial Budget Period: For a new Center, the first period of requested support should be from the requested start date through November 30 of that calendar year. (The common budget period for all funded GCRCs is December 1 through November 30). For competing continuation (renewal) applications, the first budget period should be 12 months.

Itemize specific needs for the first budget period as follows:

1. Personnel: Follow instructions carefully in the Form PHS 398 Kit. In the justification, briefly describe the function of each position, and whether support is requested. List the holder of each position by name if the position is filled and indicate whether employed by the university or hospital. All salaries requested must be consistent with institutional standards, applied regardless of the source of funds. If any support is requested for an employee of the Department of Veterans Affairs (VA), see NIH Guide for Grants and Contracts, Vol. 18, No. 27, August 11, 1989.

   For nursing and research bionutrition personnel requested, indicate the shift coverage the nursing and research bionutrition staffs will provide. Describe any unusual nursing and research bionutrition duties such as staffing for extended outpatient studies. If research bionutrition staffing is proposed, provide the following table:

Meals	% Current*	% Proposed
Planned, calculated, or modified		
Prepared or cooked		
Served		

* renewal applications only

2. Equipment: List separately each item of fixed and movable equipment requested. Provide a separate narrative justification for each equipment item requested and indicate which of the investigators and projects require the equipment and projected utilization by projects.

3, 4, 5, 6. Supplies, Travel, Alterations and Renovations, and Other Expenses: See Guidelines for the GCRC Program for details on which items may be requested.

7. Patient Care Costs: The patient care costs requested in the application for inpatients and outpatients should be supported by computations provided within the following pages.

PATIENT CARE COMPUTATION: (Figures to be rounded to the nearest dollar)

INPATIENT

RATE USED

1. If proposed rate is used, show date filed with HHS:
   MO _____ DAY _____ YEAR _____

2. If rate has been published by HHS, show date of agreement:
   MO _____ DAY _____ YEAR _____

3. Show 12-month period of rate: _____ through _____

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4. A. Routine Cost (or Space Cost for per diem method, if applicable): $_____
   B. Per Diem Method:
   __*__ Category A days x $_____ = $_____
   C. Scatter Beds:
   __*__ Category A days x $_____ = $_____

   Total (4A and 4C or 4B and 4C) $_____

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5. Service Patient Credit (routine method)
   __*__ Category B days x $_____ = $_____
   __*__ Category C days x $_____ = $_____
   __*__ Category D days x $_____ = $_____
   All Other Inpatient Credits
   (Specify: grants, contracts, industry, etc.) $_____

   Total Credits ($_____)

---

6. Inpatient Ancillaries Required Solely for Research Purposes, Adjusted to Cost (Schedule 1)

   __*__ Category A days x $_____ = $_____
   __*__ Category B days x $_____ = $_____

   Scatter Beds:
   __*__ Category A days x $_____ = $_____
   _____ Category B days x $_____ = $_____

   Total Inpatient Ancillaries $_____

---

7. Other Costs (Specify: drugs, raw food, special diets, outside laboratories, etc. Provide justification) $_____

8. TOTAL INPATIENT REQUEST

(Boxes 4, 6, and 7, less box 5) $_____

OUTPATIENT

9. Space Charge (If not included with inpatient routine costs) $_____

10. Outpatient Ancillaries Required Solely for Research Purposes, Adjusted to Cost (Schedule 2)

__*__ Category A visits x $_____ = $_____
__*__ Category B visits x $_____ = $_____

Total Outpatient Ancillaries $_____

11. Other Costs (Specify: drugs, raw food, special diets, outside laboratories, etc. Provide justification) $_____

12. Credits

__*__ Category B visits x $_____ = $_____
__*__ Category C visits x $_____ = $_____
__*__ Category D visits x $_____ = $_____
All Other Inpatient Credits (Specify: grants, contracts, industry, etc.) $_____

Total Credits ($_____)

13. TOTAL OUTPATIENT REQUEST (Lines 9, 10, and 11, less line 12) $_____

TOTAL PATIENT CARE REQUEST (Lines 8 and 13) $_____

* list total annual projected number of days and visits in each category including those which require no ancillaries

Schedule 1 — Category A Inpatient Projects*

Investigator Name	Project Title	Number Days Per Year	Annual Cost** For Tests: Hospital Ancillaries	Annual Cost** For Tests: Outside Ancillaries
	Total			

(Total ancillary costs for A days divided by A days equals average research ancillary cost per A day)

* List all projects including those for which no ancillary support is requested.
** Charges adjusted to cost by category per Patient Care Rate Agreement.

Schedule 2 Category B Inpatient Projects*

Investigator Name	Project Title	Number Days Per Year	Annual Cost** For Tests: Hospital Ancillaries	Annual Cost** For Tests: Outside Ancillaries
	Total			

(Total ancillary costs for B days divided by B days equals average research ancillary cost per B day)

* List all projects including those for which no ancillary support is requested.
** Charges adjusted to cost by category per Patient Care Rate Agreement.

Schedule 3 Category A Inpatient Scatter-bed Projects*

Investigator Name	Project Title	Number Days Per Year	Annual Cost** For Tests: Hospital Ancillaries	Annual Cost** For Tests: Outside Ancillaries	Annual*** Scatter-bed Research Nurse Hours
	Total				

(Total ancillary costs for A scatter-bed days divided by A scatter-bed days equals average research ancillary cost per A scatter-bed day)

* List all projects including those for which no ancillary support is requested.
** Charges adjusted to cost by category per Patient Care Rate Agreement.
*** Only include hours of nurses paid directly by the GCRC grant, not nurses included in a per diem charge.

Schedule 4 Category B Inpatient Scatter-bed Projects*

Investigator Name	Project Title	Number Days Per Year	Annual Cost** For Tests: Hospital Ancillaries	Annual Cost** For Tests: Outside Ancillaries	Annual*** Scatter-bed Research Nurse Hours
	Total				

(Total ancillary costs for B scatter-bed days divided by B scatter-bed days equals average research ancillary cost per B scatter-bed day)

* Include in this Schedule both those projects which involve scatter-bed B days (with entries to be made in all columns), and those scatter-bed B projects where there are no ancillary costs charged to the GCRC grant (with no entries to be made for days and ancillaries, but entries to be made for the other columns).

** Charges adjusted to cost by category per Patient Care Rate Agreement.

*** Only count hours of those nurses paid directly by the GCRC grant.

Schedule 5 Category A Outpatient Projects*

Investigator Name	Project Title	Average Duration of Visit	Number Visits Per Year	Annual Cost For Tests** Hospital Ancillaries	Annual Cost For Tests** Outside Ancillaries
			Total		

(Total ancillary costs for A visits divided by A visits equals average research ancillary cost per A visit)

* List all projects including those for which no ancillary support is requested.
** Charges adjusted to cost by category per Patient Care Rate Agreement.

Schedule 6 — Category B Outpatient Projects*

Investigator Name	Project Title	Average Duration of Visit	Number Visits Per Year	Annual Cost For Tests** Hospital Ancillaries	Annual Cost For Tests** Outside Ancillaries
			Total		

(Total ancillary costs for B visits divided by B visits equals average research ancillary cost per B visit)

* List all projects including those for which no ancillary support is requested.
** Charges adjusted to cost by category per Patient Care Rate Agreement.

[Note that in the tables on the preceding six pages, numbers of days and visits required annually for each project in the application are to be entered. Later in the application, this information is requested again when each project is described, and again in Table E for those projects to be presented at the site visit. Make sure that the numbers are consistent for a given project at each place in the application.]

B. Budget for Entire Proposed Period of Support: Provide a justification for any changes, as explained in Form PHS 398.

Additional Pages
(Form PHS 398)

PART II. BIOGRAPHICAL SKETCHES

A. Arrange the biographical sketches in alphabetical order. Provide biographic sketches for the Principal Investigator, the Program Director, Associate and Assistant Program Director, all professionals for whom salary support is requested, and the principal investigator and co-investigators of each project in the application. Restrict the list of publications in each sketch to those of the last five years (although indicating the total number of lifetime publications) and limit the entire sketch to two pages.

B. Other Support: This information should be submitted for all professional staff for whom salary support is requested from the GCRC grant and all principal investigators and co-investigators of all submitted protocols. Follow instructions in Form PHS 398. Note that if any of these individuals is the principal investigator or a co-investigator of a project to be presented at the site visit, this information is requested again in Table E. Make sure the information is consistent at both places in the application Provide the full grant number (e.g., 2 R01 HL51618-04) but a discussion of scientific overlap is not required.

PART III. RESOURCES AND ENVIRONMENT

A. Background and Introductory Statement

This section describes the institutional environment for research, both current and historical. Relevant information may include the following:

1. Briefly describe the origin of the institution and its past contributions to research, especially clinical research. Describe the interaction between basic and clinical departments.

2. Components or affiliates of the institution relevant to the proposed clinical research effort: graduate schools, medical and dental schools, schools of allied health science, hospitals, research laboratories, and government institutions.

3. Current assets for research: number of full-time faculty members involved with research, current annual grant and contract support, major endowment funds, funded Centers, etc.

4. Patient resources available for research: population and catchment area and number of admissions, inpatient days, and outpatient visits provided by the hospital or medical center.

5. Institutional assets for research training: number of medical and dental students, allied health science students, house officers, and postdoctoral fellows; nature of institutional funds for training.

B. Organizational Framework

The organizational structure of the institution should be defined as it relates to the GCRC, including the chain of professional and administrative responsibility. If these relationships involve another corporate entity (hospital, medical school, research institute, local government, etc.), describe the lines of authority and submit a letter of agreement signed by the responsible officer of each organization which supports the grant stating that the research area will be available on a continuing basis.

C. Administration

Describe the administrative structure under which the GCRC will operate, including the responsibilities of the Program Director(s), the local GCRC Advisory Committee (GAC) and its Subcommittees, and any other Committees with advisory roles on specific aspects of the GCRC's clinical research projects, such as the Institutional Review Board for Human Experimentation (IRB). Provide a membership list, with academic titles, for each committee. Describe the administrative relationship among the Principal Investigator, Program Director, and local GAC.

Indicate the procedures for coordination among Principal Investigator, Program Director, GAC, and individual investigators regarding patient care responsibilities and review and approval of submitted research projects. Describe the process for peer review or audit of the classification of research patients as Category A, B and/or D. Describe the process by which the GAC reviews and designates industry-related research patients as Category A, B and/or D.

D. Patient Care

Delineate responsibilities for medical care delivery by investigators and Program Director's oversight of medical care and research projects. Describe existing mechanisms to assure compliance with IRB-approved projects and witnessing of informed consent. Describe role of interns, residents and fellows in patient care and emergency coverage.

E. Training and Career Development

Describe the role of the GCRC as an institutional resource in the clinical research training and career development of medical students, house officers, research fellows, and paramedical personnel. In competing renewal applications, summarize previous work by CAPs and MCAPs, as well as their current academic positions, research support, and percent of effort devoted to basic and clinical research, teaching, patient care, and administration.

F. 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, 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 critical 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.

The GAC is responsible for reviewing the Core Laboratory to assure that its 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.

The application should justify the requested Core Laboratory resources in terms of the collective future resource needs of the investigators. Examples of requested Core Laboratories include those used for mass spectrometry determinations, magnetic resonance imaging, body composition determinations, and others. To allow an adequate evaluation of the Core Laboratory request, the following information must be provided, either for the most recent, complete 12-month period in a competing renewal application, or as projected in a new application:

1. The number and size of rooms used as Core Laboratories;

2. Type and number of laboratory analyses performed and proposed for the Core Laboratory, and an analysis for each test according to the percentages which have been and are proposed to be performed for each investigator or investigator group. In existing units, laboratory log books may be examined at the site visit;

3. Description of the criteria for deciding the types of analysis to be performed in the Core Laboratory. Role of GAC in this process. The number of investigative groups for whom specialized studies will be run;

4. Relationship to Program Director's laboratory;

5. Future changes in research direction or expected GCRC activity which will alter Core Laboratory requirements;

6. Role and qualifications of Core Laboratory Director and, if requested, justification for level of support requested for that position. See Guidelines for additional information as to level of support permitted;

7. Role and qualifications of Core Laboratory support staff.

G. Biostatistical Support

Provide a brief description of project review by the GAC and provisions for review of biostatistical design and subsequent data analysis. Tell how much support for a biostatistician is requested, provide qualifications of the individual, the mechanisms by which the biostatistician will interact with investigators and the role to be assumed in research project design and analysis.

H. Informatics Core

The application should justify the requested Informatics Core resources in terms of the collective future resource needs of the investigators. The Informatics Core is to meet database management, special applications and analysis needs of GCRC-based investigators. Careful consideration should be given to the system configuration to facilitate investigator access to the software systems. To allow an adequate evaluation of the Informatics Core request, the following information must be provided, either for the most recent complete 12-month period in a competing renewal application, or as projected in a new application:

1. Provide a narrative justification for the space required to accommodate all functions of the Informatics Core.

2. Provide a narrative justification for the equipment selected and upgrades that are needed. The narrative justification for the system should reflect both the resource need and scientific merit of the GCRC-based research projects conducted by investigators who receive primary research funding from NIH and other peer-reviewed awards. The multi-user resource must reflect multidisciplinary and multicategorical clinical research.

3. Provide brief narrative summaries of those scientific studies which will use the Informatics Core and indicate how the Informatics Core will facilitate the progress of the research

projects. All studies utilizing Informatics Core resources must have GAC approval. In instances where investigators conducting off-center clinical research request access to the Informatics Core, the proposals need to be reviewed for scientific merit and the GAC needs to assign priority for access to the Informatics Core. In all cases, NIH-funded clinical research receives the highest priority.

4. Describe the future changes in research direction or expected GCRC activity which will impact Informatics Core resource requirements.

5. Describe the selection process and qualifications of the Informatics Core Manager and justify the level of support which is requested for the position.

6. Describe the duties of the Informatics Core Manager which should include:

a) close interface with the GCRC-supported Biostatistician to assure adequate data management and analysis support to GCRC-based investigators;

b) close interaction with Administrative Manager to prepare the administrative components of reports required by NCRR and NIH;

c) ensuring adequate hardware and software maintenance and upgrades through interactions with informatics specialists and vendors, including negotiation and maintenance of hardware and software contracts;

d) maintaining security of the physical facility, equipment, data files, and file backups and storage;

e) instruction of and assistance to clinical investigators in the use of Informatics Core resources. However, the Informatics Core Manager is not required to carry out routine data analyses for investigators or the GCRC Biostatistician;

f) administering the resources for the Informatics Core, including ordering of supplies and upgraded equipment. Charges to Informatics Core users are not allowable for Category A and B research. Prorated fees for Category D research and off-center clinical research, are to be collected and credited to the patient care category of the GCRC grant.

I. Physical Resources and Utilization

Describe the GCRC facility in sufficient detail to identify each physical component. Include schematic line drawings, reduced to the size of the continuation pages, and identify the size and use of each room. Indicate the present room arrangement and use if renovation is proposed.

If space charges are proposed as a separate cost or as part of the routine cost, include a list detailing use and square feet of each room/area to be on the GCRC. If there are GCRC areas that will not be charged to the grant, indicate which areas. In addition, provide a tabular list of rooms to be used for inpatient and outpatient studies. Whether the outpatient area is separate from inpatient area or if inpatient rooms are also used for outpatient visits, indicate which rooms, projected number of visits, length of visits and average number of hours per day and days per week.

J. Other Existing or Planned Resources for Clinical Research

Attach a brief description of all available or projected facilities for clinical research at the institution and affiliated institutions; for example, GCRCs, categorical Clinical Research Centers, privately funded research wards, etc.. Describe the location and number of beds in these facilities and explain their projected relationship to the GCRC requested in this application.

Section 2
(Form PHS 398)

PART IV. RESEARCH PLAN

A. Accomplishments

In competing continuation applications, or in applications for support of a GCRC which has previously been funded from other sources, summarize scientific accomplishments from use of the GCRC since the last review. Accomplishments selected should represent advances or achievements that led to the prevention of disease, provided a better understanding of a disease process or of a physiologic mechanism, provided a new or better therapeutic approach, or resulted in a new methodology either for the early detection or diagnosis of disease. Describe outcomes of clinical trials. Describe contributions to multicenter trials. The narrative should clearly describe each accomplishment, its originality, and significance in terms of the above categories. For each accomplishment, provide the relevant publication reference(s). If the accomplishment has found application in the health care system, point this out. Describe any findings which result in more cost-effective approaches to diagnosis or therapy. The Accomplishments section should not exceed five pages.

B. Center Bibliography (Competing Continuation Applications Only)

For Center renewal applications, cite only published papers. Include scientific articles which resulted in whole or in part from investigations undertaken with GCRC resources since the last funded application. Omit publications which are in press or have been submitted but not yet accepted, and papers in preparation. Include names of all authors in the same order as they appear in the journals, as well as titles of articles, volume numbers, inclusive pages and

year of publication. Asterisk those papers which cited the GCRC, i.e., either mentioned use of the GCRC in the text, or cited the GCRC (M01) grant number.

Review articles, books, and abstracts may be cited, but should be listed separately. If research reported in an article was aided by GCRC support but did not use inpatient or outpatient facilities (e.g., Informatics Core resources), indicate this in a footnote.

C. Research Projects

Include each research project proposed for use of the GCRC including projects already under way at the time of the application. List them by project principal investigator, in alphabetical order. Exclude completed or inactive projects. All projects to be presented at the site visit must be included, even if they are awaiting approval by the GAC or the IRB at the time of submission of the application. Indicate by a footnote those projects not yet approved at the time the application is submitted. Approval must be obtained from those committees within 60 days of submission or prior to the site visit, whichever occurs first. Only IRB-approved projects may be reviewed at the site visit, and this means full, final (not "provisional") IRB approval including possessing an IND approval from the FDA if an IND is required.

The total page limitation of the application specified in the instructions of Form PHS 398 do not apply to GCRC applications. The length of projects selected for presentation at the site visit may not exceed 25 pages, and the length of non-presented projects may not exceed 5 pages. These page limitations are inclusive of Specific Aims, Background and Significance, Progress Report and Preliminary Studies, and Research Design and Methods sections. For literature citation follow instructions in the Form PHS 398 Kit. Each project should include a clearly identifiable hypothesis, brief background information, and an in-depth narrative of the methodology to be employed. Provide details of biostatistical design and analysis for each project. Address each of the six points listed under Human Subjects in the Form PHS 398 Kit for each project.

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects unless a clear and compelling rationale and justification is provided documenting that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy is based on the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and is available electronically at http://www.nih.gov/grants/guide/1994/94.03.18/. It is further discussed in documents entitled, "Outreach Notebook for the NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research, August 1994," and "Questions and Answers Concerning the 1994 NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, September 7, 1994." To comply with this policy, the following "three table" format with text between table 2 and table 3 may be used. The first table should give the national demographics of the disease under study. For example, if rheumatoid arthritis were being studied, the first table would be as follows:

National Demographics for Citizens Afflicted with Rheumatoid Arthritis (%)

	American Indian or Alaskan Native	Asian or Pacific Islander	Black, not of Hispanic Origin	Hispanic	White, not of Hispanic Origin	Other or Unknown	Total
Female	0.3	0.7	15.3	1.9	51.3	4.1	73.6
Male	0.1	0.2	3.0	0.4	21.0	1.7	26.4

The numbers presented in the first table should represent percentages of the total number of rheumatoid arthritis patients in the United States who fall into the listed demographic categories. For example, of those with rheumatoid arthritis in the United States, 51.3% are white females and 3.0% are black males. Following the table, a reference listing the source of the information should be identified in full.

The second table should indicate the patient distribution that would be anticipated in the protocol if no special recruiting efforts were to be made. These data can reflect either numbers of research subjects or percentages thereof and represent: a) the patients recruited into this protocol to date, b) the recruitment into a forerunner of this protocol, c) the demographic distribution of all rheumatoid arthritis patients seen at the hospital, or d) the demographic distribution of all rheumatoid arthritis patients in the city or State. It should be indicated whether the data are characterized as a, b, c or d.

Table 2 should then be compared to Table 1. If the numbers listed in Table 2 are substantially lower in minorities overall or in women, then a plan should be described that will appropriately increase the participation of the relevant groups.

Table 3 should present numbers of research subjects, not percentages. The total number should be that which the investigator's power calculation indicated as the final number of subjects to be recruited into this protocol. The numbers within Table 3 should reflect the anticipated result of the plan for gender and minority recruitment and, when totaled, equal the final number of subjects. If Table 2 for this protocol is close to or surpasses the National demographics in terms of overall minorities and women, then the Table 3 data can be adapted from Table 2. However, if the data in Table 2 are far below the National demographics in terms of minorities overall and women, then the Table 3 should reflect the outreach plan to recruit the appropriate patients. Protocols specifically designed and approved to study only one minority group(s) or one gender are excepted from this guideline.

The NIH recently announced a policy that children, defined as individuals under the age of 21, must be included in all human subjects research conducted or supported by the NIH. Adherence to this guideline is mandatory unless there are scientific or ethical reasons to exclude children from a specific study. The policy is available electronically at:

http//www.nih.gov/grants/guide/notice-files/not98-024.html. In contrast to the Women and Minorities Policy, which applies to all applications, the Inclusion of Children Policy applies only to initial (type 1) applications.

In addition, for each project, provide a justification for utilization of GCRC resources, along with an estimate of the number of research patients to be studied and the number of research inpatient days and outpatient visits (categories A, B and D) and other GCRC resources (e.g., Core Laboratory, Informatics Core , etc.) to be used annually. Provide a summary of anticipated charges by inpatient day and/or by outpatient visit for ancillary costs for each project. Additionally, provide a summary of other research needs to be provided by the individual investigator's laboratory or outside laboratories. Federal and non-federal grants, contracts, or other support held by investigators conducting the proposed study should be identified by project together with a indication of whether they relate directly to the proposed study. Indicate the grant/contract number, source of support, and inclusive period of support.

Patients studied in industry-initiated projects are classified as Category D (see Guidelines). All charges of those protocols are to be paid directly to the institution (hospital). No charges are provided by the GCRC, but discrete GCRCs receive patient care offsets determined for inpatient days by the Patient Care Agreement developed by the regional HHS office.

Each project narrative should be followed by a current bibliography supporting the hypothesis, background, and methodology, including references to papers and abstracts which have resulted from previous work by the investigator submitting the project and references to the work of others. This bibliography is essential for an adequate review.

Each project in the application to be presented at the site visit must be accompanied by a brief (one-half to one page) abstract or summary of the project proposed for the GCRC. The abstract will serve as the basis for the description of the proposal which will be incorporated into the Site Visit Report reviewed subsequently by the GCRC Review Committee, and the Summary Statement reviewed subsequently by the NARRC. The summaries should be appended to the site visit schedule which is sent at the same time the proposal is submitted to the NCRR.

PART V. TABLES

TABLE A. Faculty Member Research Participation (Instructors and above). List the number of faculty members in each Department and their percent of effort devoted to research.

Example
TABLE A
Faculty Member Research Participation

Number of Faculty Members			Number of Faculty Members Devoting the Indicated Percent of Effort to Research	
DEPARTMENT	FULL-TIME	*PART-TIME	5 - 50	Above 50
Medicine				
Surgery				
Ob-Gyn				
Pediatrics				
Other Clinical Departments				
Pre-Clinical Departments				
TOTALS				

*Salaried

TABLE B. Training. Complete Table B, below. Do not include house officers (interns and residents).

Example
TABLE B
Fellows in Training

DEPARTMENTS	Number of Post-Doctoral Fellows	
	M.D.	Ph.D. or equivalent
Medicine		
Surgery		
Pediatrics		
Ob-Gyn		
Other Clinical Departments		
Pre-Clinical Departments		

1. Provide a list of all funded institutional training grants, by department or division, including grant numbers, Principal Investigators, funding sources, and inclusive dates of support.

2. For competing continuation applications, provide the name(s) of all CAPs and MCAPs supported at the GCRC at present and in the past, inclusive dates of support, specialty, and a description of their current professional activities and academic affiliations. If possible, provide information as to whether those individuals are currently funded as Principal Investigators or Co-Investigators of research grants.

3. Provide a description of the opportunities for medical students to work with GCRC-based investigators and their projects. Provide a summary of medical students supported by GCRC-based investigators. Separately provide a detailed list of medical students (by name and year), supported totally or in part by GCRC resources since the time of previous GCRC review.

TABLE C-1. Utilization of the Center, Last Three Years (for competing continuation applications and applications from Centers previously funded from other sources). Indicate the number of Category A and Category B days on the Center, scatter-bed days off the Center, and outpatient visits for each of the last three years of the grant. Provide the average length of patient stay. Centers with separate adult and pediatric units subsumed under one grant must submit separate tables for each unit.

Example
TABLE C-1
Utilization of the Center, Last Three Years
INPATIENT DAYS

Year	Category A	Category B	Scatter Bed A	Scatter Bed B	Category D	Category C	Average Length of Inpatient Stay
1994-1995							
used:	1,100	1,200	25	300	400	0	4.5 days
awarded:	1,090	1,220	25	100	400	0	
1995-1996							
used:	etc.						
awarded:							
1996-1997							
used:	etc.						
awarded:							

Indicate number of days for all categories.
Category A: Research patients or normal controls.
Category B: Patients receiving established medical care and participating in a research project. All research costs are paid by the GCRC or from the investigator's research support.
Category D: Industry-initiated research project. All charges paid by industry directly to institution.
Category C: Non-research patients who are boarders on discrete Centers.

Example
TABLE C-2
Utilization of the Center, Last Three Years

OUTPATIENT VISITS

Year		Outpatient Visits A	B	D
1994-1995	< 1 hour	500	500	500
	1 - 3 hours	500	500	500
	3 - 6 hours	75	75	75
	6 -10 hours	75	75	75
	>10 hours	75	75	75
	TOTAL (USED)	1,225	1,225	1,225
	AWARDED	1,000	1,000	1,000
1995-1996	< 1 hour	500	500	500
	1 - 3 hours	500	500	500
	3 - 6 hours	75	75	75
	6 -10 hours	75	75	75
	>10 hours	75	75	75
	TOTAL (USED)	1,225	1,225	1,225
	AWARDED	1,000	1,000	1,000
1996-1997	< 1 hour	500	500	500
	1 - 3 hours	500	500	500
	3 - 6 hours	75	75	75
	6 -10 hours	75	75	75
	>10 hours	75	75	75
	TOTAL (USED)	1,225	1,225	1,225
	AWARDED	1,000	1,000	1,000

M01-RR-_____ Principal Investigator/Program Director:_____

TABLE D-1. Principal Users of the Center (for competing continuation applications and for applications from GCRCs previously funded from other sources). List approximately ten investigators who have used the most research inpatient days and outpatient visits by grant year for the last three grant years. Provide Category A, B, and D days and outpatient visits separately. If investigators have left the institution, footnote the year of departure.

Example
TABLE D-1
Principal Users of the Center

INPATIENT DAYS

		1994-1995					1995-1996					1996-1997				
Investigator	Department	Category			Scatter-bed		Category			Scatter-bed		Category			Scatter-bed	
		A	B	D	A	B	A	B	D	A	B	A	B	D	A	B

Example
TABLE D-2
Principal Users of the Center

OUTPATIENT VISITS

Investigator	Department	1994-1995 Category A	B	D	1995-1996 Category A	B	D	1996-1997 Category A	B	D

TABLE E. Proposed Scientific Agenda for the Site Visit and Abstract Package.

For each project to be presented at the site visit, provide the following information.

1) The title of the project and the page number at which it begins in the application.

2) The name, degree (M.D. or Ph.D.) and title of the principal investigator and all co-investigators, and the page numbers at which their biographical sketches begin in the application.

3) All sources of support for each investigator and co-investigator along with percent effort, with inclusive dates and approximate current annual dollar amounts, supporting the work of these investigators, regardless of whether the funding is related to the project to be presented at the site visit. Asterisk those sources of funding which directly support at least some aspects of the research project. Include support from portions of Program Project and Center grants. For each source of support cited, provide all information as required in the Form PHS 398 including the name of the principal investigator of that grant.

4) List the resources required annually from the GCRC (inpatient days and outpatient visits by category, Informatics Core, Core Laboratory, biostatistician, and bionutrition research).

5) Provide a 1/2 to 1 page abstract of the project.

EXAMPLE
Proposed Scientific Agenda for the Project Site Visit

1. Clinical Studies of the Mechanism of Spherical Missile Transfer. (Protocol p. 372)

Joseph B. Tinker, M.D., Professor of Surgery (C.V. p. 119)

John S. Evers, M.D., Ph.D., Associate Professor of Anesthesiology (C.V. p. 44)

Frank L. Chance, M.D., Assistant Professor of Medicine (C.V. p. 29)

NICHD Program Project P01 CA67182, $25,000, Dr. Chance 15% effort

(P.I. of Program Project, Harry M. Steinfeldt, M.D.)
(Jan. 1, 1998 to Dec. 31, 2002; annual budget $250,000)

Resources required:	130 Category A inpatient days
(annually)	75 Category B inpatient days
	10 Category A scatter-bed days
	50 Category A outpatient visits (1-2 hours)
	10 Category A outpatient visits (10-12 hours)

50 Category B outpatient visits
Informatics Core (SAS, Ingres, PROPHET, etc.)
Core Laboratory (200 insulin determinations)
Biostatistician
Bionutrition Research

Abstract of project.

Section 3
(Form PHS 398)
Appendix

Do not include substantive materials in appendices.

SITE VISIT INFORMATION

I. SITE VISIT DATE

The Scientific Review Administrator (SRA) of the GCRC Review Committee is responsible for determining the need for a site visit. In general, new and renewal GCRC applications will be site visited. Occasionally, if needed, a complex supplementary application may be site visited. In some cases, an "applicant interview" (reverse site visit) may be held. Site visit dates are scheduled by the assigned site visit SRA usually months prior to submission of the grant application. Site visits will take place between 30 and 80 days after submission of the application; Program Directors should alert investigators who will be presenting at the site visit of this time-frame.

II. ADVANCE MATERIAL

Additional information is required to supplement the application and to allow for the preparation of the site visit. The following information should be sent directly to the site visit SRA: two copies of the proposed site visit agenda and abstract package, containing the project information from Table E of the application, arranged according to the schedule described below, and a diskette containing the abstracts of the protocols to be presented at the site visit. Indicate building, room number and address where site visit will be held. (Applicants should examine Supplement III to the GCRC Guidelines, "Information and Instructions for Site Visitors on a GCRC Site Visit," so that they will be aware of the kind of information reviewers will be seeking.)

III. SITE VISIT AGENDA for most GCRCs.

The following is a suggested site visit schedule.

DAY 1:	7:45 a.m.	Preliminary executive session of site visitors.
	8:15 - 9:00 a.m.	Brief outline by the Principal Investigator and Program Director of GCRC activities since the last review (renewals only) and proposed future utilization. Overview of resources which impact GCRC.
	9:00 - 9:30 a.m.	Core Laboratory Presentation (if applicable)
	9:30 - 10:00 a.m.	Informatics Core Presentation and justification and role of Biostatistician (if applicable)
	10:00 - 10:15 a.m.	Break
	10:15 a.m.	Administrative meeting of administrative reviewer with institutional officials (concurrent with scientific presentations).
	10:15 - 10:45 a.m.	Scientific Presentation #1
	10:45 - 11:15 a.m.	Scientific Presentation #2
	11:15 - 11:45 a.m.	Scientific Presentation #3
	11:45 - 12:15 p.m.	Scientific Presentation #4
	12:15 - 1:00 p.m.	Lunch
	1:00 - 1:45 p.m.	Tour of Facilities
	1:45 - 2:15 p.m.	Scientific Presentation #5
	2:15 - 2:45 p.m.	Scientific Presentation #6
	2:45 - 3:15 p.m.	Scientific Presentation #7
	3:15 - 3:45 p.m.	Scientific Presentation #8
	3:45 - 4:00 p.m.	Break
	4:00 - 6:30 p.m.	Executive Session
DAY 2:		
	7:30 - 11:30 a.m.	Executive Session

For very large GCRCs**,** presentation of an additional project at the site visit may be considered.

This must be cleared in advance with the site visit SRA. Questions arising during the executive session may require a meeting with the Program Director, who should remain available until the site visit team leaves the institution.

IV. SCIENTIFIC CONTENT

Eight scientific presentations will usually suffice for most Centers. An additional presentation may be considered under exceptional circumstances. Consultation with the site visit SRA is required before more than eight presentations can be scheduled. Projects which will account for extensive utilization of the GCRC resources are those to be selected for presentation. The projects presented should account for a significant fraction of requested inpatient days and outpatient visits and also reflect requests for other resources (Informatics Core, Core Laboratory, bionutrition, etc.). Industry-initiated projects shall not be presented at the site visit; multicenter trials may be presented only if the investigator at your institution originated the trial or has added unique features to the project, not being conducted at other Centers, and only after discussion with the site visit SRA.

A. Project presentations are to be hypothesis-oriented investigations requiring a significant number of inpatient days, outpatient visits, or Core Laboratory facilities. All projects must have Institutional Review Board (IRB) approval within 60 days of submission of the GCRC proposal or have IRB approval prior to the site visit, whichever occurs first. "IRB approval" means full, final IRB approval including possessing an approved IND from the FDA, if an IND is required. If a project has not been approved by the IRB, the protocol and request for support will be withdrawn from review automatically.

B. Scientific presentations should be limited to 15 minutes, with 15 additional minutes for discussion between site visitors and investigators.

C. Presentations may begin with a brief review of previous work (no more than five minutes) but should proceed rapidly to a clear statement of the questions proposed for future investigation. The experimental project should be described in some detail. Each presentation should consist of a description of how the GCRC will be used for the research project and a justification for requested resources (e.g., number of research inpatient days or outpatient visits by category, Informatics Core, etc.), and preliminary data.

V. ADMINISTRATIVE REVIEW

During the site visit, the consulting administrator (sometimes accompanied by an NCRR staff representative) will meet with hospital and university officials to discuss budgetary and management procedures, physical facilities, staffing, personnel functions, and other operations pertinent to the unit; they will also discuss GCRC operations with the Head Nurse, Research Bionutritionist and Administrative Manager. These discussions will be held separately from the scientific meetings. Architects and plant management personnel should be present when changes in the physical facility are requested.

VI. ADDITIONAL SITE VISIT MATERIAL

To aid reviewers, it would be helpful if the following information is made available for examination during the site visit.

A. Consent forms for all projects in the application (all are to have full, final IRB approval).

In addition to all consent forms required to be available for examination at the site visit, two copies of all consent forms will be requested to be sent to the NCRR Office of Review (OR) shortly after the application has been received, and the consent forms will then be sent out to the site visitors for their review prior to the site visit. If the title of the consent form is not identical to the title of the corresponding protocol, or if there is more than one consent form for a given protocol, or more than one protocol for a given consent form, this must be clearly indicated when the consent forms are submitted to OR. Indicate the IRB number and protocol number on the consent form. Provide a master list index of all consent forms indicating the date of initial IRB approval and the date of the most recent annual IRB re-approval of the protocol.

B. Copies of scientific protocols, contracts, and budgets of all industry-related projects which currently use or anticipate utilization of GCRC resources, including Informatics Core-only or Core Laboratory-only projects. Documents are to be available for both investigator-initiated and industry-initiated projects.

C. IRB records, including minutes. Site visitors are representatives of the Department of Health and Human Services, and as such are authorized to inspect and copy IRB records at reasonable times and in a reasonable manner. It is essential that the representatives be given sufficient access to records to assure themselves that IRB activities are being carried out in accordance with the Federal Regulations for the Protection of Human Subjects, as described in 45 CFR 46.

D. GAC minutes.

E. If GCRC funds are used for animal-related research activities (e.g., antibody generation, harvesting cells or other tissues), at least one of the site visitors will visit the institution's animal facilities during the course of the site visit.

F. Tabular summary of research funding, by grant or contract, to investigators for projects presented at the site visit, as well as a separate table for those investigators with projects not presented at the site visit. The format requested in Form PHS 398 is to be provided

G. Tabular summary of requested annual Categories A, B, and D research inpatient days and Categories A, B, and D outpatient visits by project for those presented at the site visit, as well as a separate table for those projects not presented. Indicate whether the Core Laboratory or Informatics Core resources are requested for each project.

H. Inpatient occupancy and outpatient statistics for the months since Table C was prepared.

I. One copy of the institution's catalog.

J. Biographical sketches of all major investigators not listed in the application, such as new arrivals.