

**General Clinical Research Center Submission and Format Requirements
for the GCRC Advisory Committee
University of Kansas Medical Center**

The GCRC is available to all clinical researchers at the University of Kansas Medical Center (M.D., D.O., Ph.D, RN, PT, OT, RD, and others) who wish to conduct patient-oriented research. The primary investigator may be a KUMC investigator from the School of Medicine, Nursing, or Allied Health.

Investigators who plan to use GCRC resources are strongly encouraged to submit their applications for review of a new research project to the GCRC Advisory committee before submission of that project to the Human Subjects Committee (HSC). Ongoing projects already approved by the HSC will need to be submitted for review by the GCRC Advisory Committee. The project must have approval by both committees prior to implementation on the GCRC (see flowsheet on page 2). Following approval, an implementation meeting is required for protocol activation. Please contact the GCRC for assistance and answers to any questions regarding submission process or the steps to protocol activation (see checklist on page 3). Investigators are strongly encouraged to consult with the biostatistician early in the planning of your study. This may not only make your study more effective, but may also prevent any possible delays in final approval.

Protocols submitted to the GCRC must follow the NIH/PHS format (see website <http://grants.nih.gov/grants/funding/phs398/phs398.html>). Protocols are reviewed for scientific merit and need for GCRC resources by the GCRC Advisory Committee. Please note that the primary mission of the GCRC is to support NIH-funded research projects. The GCRC also supports investigator-initiated research projects funded by other sources or pilot studies that may be unfunded. These are all considered “Category A” studies (see Appendix 1 for Categories of GCRC study subjects). Support provided by the GCRC at no charge to investigators includes research space, nursing assistance, data management, and biostatistical help. Certain routine screening and safety lab tests (e.g. CBC, pregnancy test, etc.) and ancillary supplies (e.g. IV solutions, tubing, syringes, etc.) may be supported by the GCRC budget depending on fund availability. However the GCRC should not be considered as a funding source for research protocols. In particular the GCRC does not provide funding for clinical research coordinators or investigators.

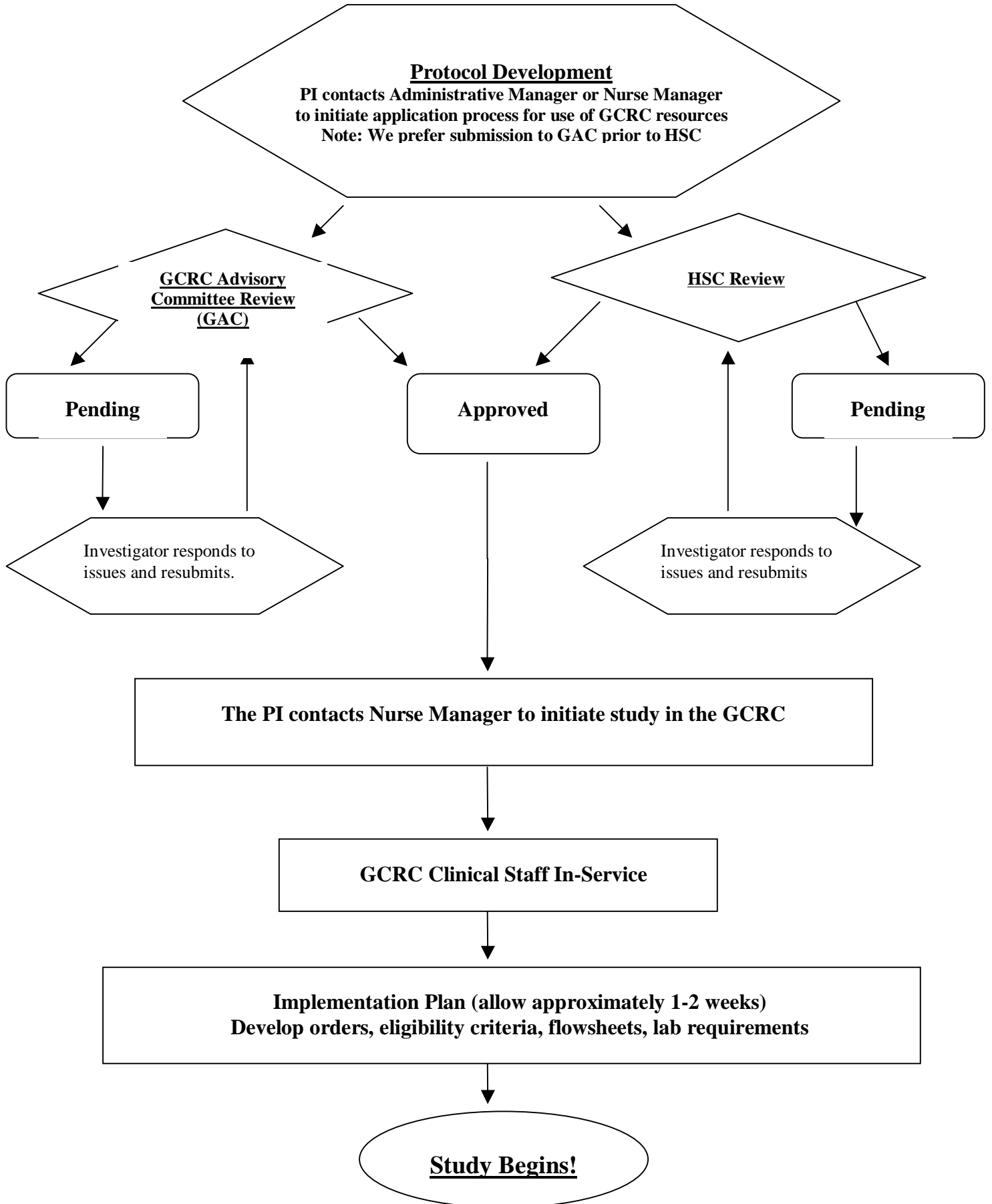
A limited number of industry supported studies “Category D “may be conducted on the GCRC. For these studies, there will be a charge to the study sponsor for space and resources. Additional requirements for industry sponsored studies are listed on page 3.

For patient safety and medical coverage issues, each project must include at least one faculty physician (M.D. or D.O.) as co-investigator. If you can’t identify a physician for this purpose, the GCRC can assist you in this.

Please remember to always cite the GCRC in your publications that result from studies that received any support from any of the GCRC resources. For example, “We acknowledge the support of the University of Kansas Medical Center General Clinical Research Center.” Once accepted, please forward a copy of the publication to the GCRC. Funding for the GCRC through the NIH/NCRR depends upon demonstration that outstanding research is being conducted and published, using GCRC services and facilities.

The GCRC Advisory Committee meets monthly on the fourth Wednesday to review protocols. The checklist on page 3 lists all the items that must be submitted by the 5th of the month to be placed on that month’s agenda. The GCRC application form begins on page 4. Please return all required items to Judy Otey, RN. Mail Stop: 2012 Fax# 913-588-6965. Email- jotey@kumc.edu.

GCRC STUDY IMPLEMENTATION FLOWSHEET



GCRC Application Checklist

1. _____ GCRC Application Checklist
2. _____ Protection of Human Subjects Checklist (Appendix 2)
3. _____ GCRC Application and 1 copy of protocol in GCRC required format*
(*The NIH protocol format required by the GCRC can be utilized when submitting the protocol to the HSC. See website <http://grants.nih.gov/grants/funding/phs398/phs398.html> for downloadable instructions and form files)
4. _____ Protocol includes Data and Safety Monitoring Section
5. _____ 1 copy of HSC application and 1 copy of consent form
6. _____ Copy of all applicable budget information
7. _____ For any clinical trial conducted under an IND/IDE, 1 copy of the investigator's brochure
8. _____ Biographical sketch (using NIH-form PHS 398 and format) for each investigator listed on the project

Note: After final approval by the GCRC Advisory Committee and HSC, the investigator will also need to provide:

9. _____ Diskette or email containing file of final approved version of protocol saved in format readable by Microsoft Word
10. _____ 1 copy of all correspondence from the HSC, including final approval letter
11. _____ 1 copy of each HSC approved consent form

Additional Requirements for Industry-supported Or Designed Research:

1. In the body of the protocol or by cover letter, indicate whether the research is industry-initiated or investigator-initiated and designed. The latter will be given much greater preference with respect to GCRC usage.
2. Is the study unique (in what way? To this institution or is it multi-centered? If multi-centered, will data be shared?) Unique studies in which work done at this institution can be published separately will be given higher priority.
3. Are there any limitations to publication? If so, it is less likely that the study will be approved for GCRC use.
4. For both forms of industry related research, the GCRC Advisory Committee will be responsible for allocating the extent to which the industry will be obligated for the support of research conducted at the GCRC.
5. _____ 1 copy of the itemized budget requested from industry
6. _____ 1 copy of the industry protocol or the protocol as approved by industry (in addition to the GCRC required format)
7. _____ 1 copy of the Industry Contract

GCRC APPLICATION

Title of Research Study (should be the exact title approved by HSC or that will be submitted to the HSC):

Principal Investigator: _____ Title: _____

Department: _____

Mailing address: _____ Phone #: _____

Fax #: _____ Pager #: _____

Email address: _____

Key Contact Person: _____ Phone #: _____

Pager #: _____ Email address: _____

KUMC HSC Approval: Not submitted____ Submitted/Pending____ Approved____ HSC#_____

Length of Study: _____year(s) Preferred GCRC start date:_____

Estimated total number of subjects (patients and normal controls):_____

Is this study a multi-center trial?_____ If yes, coordinating center:_____

Is this study a clinical trial?_____ If yes, which phase_____

Signature of Principal Investigator:_____

Date submitted to GCRC:_____

For questions regarding protocol format and/or the submission process, contact Judy Otey, Nurse Manager, or Susan Schmitz, Administrative Director.

Submit application documents to:

Judy Otey R,N,

GCRC Nurse Manager

jotey@kumc.edu

Mail Stop 2012. Fax # - 913-588-6965

STUDY FUNDING:

Please list all sources of funding, other than the GCRC resources being requested, that will be used to support this study. **Be sure to include contribution of supplies, medications, equipment, and services. Please indicate whether funding is approved or pending.** All funded and pending studies must have documentation regarding budget submitted to and budget awarded by funding agency. Please enclose a copy of the appropriate budgets.

_____ NIH/PHS (Specify):

_____ Other government (please identify):

_____ Foundation (please identify):

_____ Research Institute at KUMC:

_____ Private Industry/Investigator-Initiated:

_____ Private Industry/Industry-Initiated:

_____ Department Funds (please identify):

_____ Other (please identify):

_____ None

GENERAL CLINICAL RESEARCH CENTER
Research Protocol Format

Protocols should be single-spaced, have at least ½ inch margins in all directions, and contain characters of no less than size 10 font. Helvetica or Arial 12-point is the NIH-suggested font. Suggest 5-8 page limitation to include specific aims, background and significance, preliminary studies/progress report, research design and methods.

GCRC Protocol # _____ (will be assigned on submission)

GCRC SPID # _____ (will be assigned on submission)

HSC# _____ (if already approved)

Title of Project: (must match title on consent forms)

Principal Investigator: (Name, Degree, Department)

Co-Investigators: (Name, Degree, Department)

Abstract

One-half to one page abstract/project summary

Specific Aims

List the long-term objectives and what the proposed research will accomplish. State the hypothesis to be tested.

Background and Significance

Sketch the background leading to this study, evaluate existing knowledge, and identify gaps which this study will fill. State the importance of the research by relating the specific aims to the long-term objectives.

Preliminary Studies/Progress Report

Provide an account of the principal investigator's preliminary studies pertinent to the project and/or any other information that will help to establish the experience and competence of the investigator to pursue the proposed project.

Research Design and Methods

Describe the research design and the procedures to be used to accomplish the specific aims of the protocol. Describe any new methodology and its advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. Provide a flow diagram or timetable for the project. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

Statistical Methods

Indicate methodology for determining sample size, including the size of Type I(alpha) and Type II (beta) errors, as well as, response variable(s) of primary importance and the size of effect to be detected (e.g., 30 mg decrease in total cholesterol) with an estimate of variation (e.g., standard deviation). Specify the randomization procedure – describe in detail and identify stratification variables where appropriate. Describe the statistical methods to be used in analyzing the data (t-test, ANOVA, regression, etc) and indicate statistical software to be used (e.g., SAS) and describe any interim analysis plans. Include how the data will be collected, analyzed, and interpreted as well as the data-sharing plan as appropriate.

Protection of Human Subjects – All projects must address the following four evaluation criteria (using same heading and sub-headings):

1. Risk to the subjects -

Human Subjects Involvement and Characteristics:

Describe the proposed involvement of human subjects in the work outlined in the Research Design and Methods section. Describe the characteristics of the subject population, including anticipated number, age range, and health status. Identify criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals or others who may be considered vulnerable populations.

Sources of Material:

Identify the sources of research material in the form of specimens, records, or data.

Potential Risks:

Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects. Indicate the risk categorization (minimal, moderate, high – see Protection of Human Subjects Checklist, Appendix 2). Where appropriate, describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures to subjects in the proposed research.

2. Adequacy of Protection Against Risks -

Recruitment and Informed Consent:

Describe plans for recruitment of subjects and the process for obtaining informed consent.

Protection Against Risk:

Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse events to the subjects.

Data and Safety Monitoring Plan:

As mandated by the NIH, all protocols on the GCRC must have a Data and Safety Monitoring Plan (DSMP). Plans may vary from simple to more detailed, depending on the level of risk imposed on the research subjects. Only in specific circumstances is a formal Data Safety Monitoring Board (DSMB) required.

There are two issues regarding safety as described in sections A and B below: 1) appropriate collection, recording, and review of data, and 2) recognition and recording of adverse events and general safety review. Investigators should complete the Protection of Human Subjects Checklist (Appendix 2). By completing the checklist, investigators will gather information required for inclusion in the “Protection of Human Subjects” portion of the protocol. Include this checklist with the application.

(A) Data collection and monitoring:

The protocol must detail how data collection will occur and quality will be assured, a description of the records to be maintained, and how the study is to be monitored for adherence to the protocol. If the study is investigator-initiated, then it is likely that the PI will be responsible for organizing, tracking, and evaluating the data. This fact and the frequency of monitoring should be specified.

Indicate how data will be organized, managed, and stored (list where and how – e.g. lab notebook, software database, etc.) and by whom. Discuss how the security of the research data and the privacy of subjects will be maintained. For example, discuss the use of:

- (a) password protection on study databases and scheduled changes to passwords
- (b) encryption of data sent over the internet

- (c) access to study databases restricted to an “as-needed” basis
- (d) restricted ability to alter the data in a study database or directly view all of it without specific cause
- (e) encryption of all email or protection by password of all data with patient-identifiable Information

If the study is industry sponsored, please indicate the monitoring agency and how often the monitoring will be done. If there is a DSMB or safety committee, there should be a description of the general composition of the board, its duties, and the DSMB charter if available.

All studies should detail what data will be reviewed and the procedures for implementing changes as a result of the review. The details of what will be assessed for an interim analysis should be included if this is to be done.

(B) Safety monitoring/Adverse event reporting:

The protocol must also indicate who is responsible for safety monitoring (see below), the plan for safety review which includes when serious adverse events (SAEs) and non-serious adverse events (AEs) are reported and to whom (i.e. HSC, DSMB, GCRC, funding and regulatory agencies), and an AE grading and attribution scale.

(1) PI monitoring only: PI monitors study, with prompt reporting of adverse events and other study related safety information to the HSC, GCRC, sponsor, or other agencies, as needed. Protocol deviations and amendments also need to be reported.

Ex: This level of monitoring would be appropriate for studies with minimal to moderate risk that can be effectively monitored by the PI. These include studies involving only surveys, venipuncture, and observational studies with no high-risk procedures.

(2) PI monitoring and safety monitor: PI monitors study as noted above, with oversight by a safety monitor. This individual should have appropriate clinical and research expertise and should have no conflicts in monitoring the study.

Ex: This level of monitoring would be appropriate for moderate risk studies that may require independent safety monitoring, such as a relatively small investigator-initiated study involving a vulnerable population.

(3) PI monitoring and DSMB: PI monitors study as noted above, with oversight by a DSMB. DSMB members typically include scientists, clinicians, statisticians, and others who periodically review the safety and integrity of a study and evaluate accumulating data to consider a need for early stopping due to significant evidence of benefit, harm, or futility. DSMB members should have appropriate clinical and research expertise and should have no conflicts in monitoring the study. If DSMB is planned for this trial, please submit a copy of the DSMB charter including a description of the planned meeting frequency, how information will be distributed to investigators, and a list of the DSMB members and their qualifications.

Ex: This level of monitoring would be appropriate for larger, comparison group studies such as (a) trials involving relatively high risk of death or events in which the intervention may increase risk or cause unanticipated adverse events, (b) trials testing an agent for which little or no toxicity data in humans is available, (c) blinded trials of high-risk interventions, (d) trials with vulnerable populations receiving a high-risk intervention. All NIH-funded multicenter Phase III clinical trials must have DSMBs.

3. Potential Benefits of the Proposed Research to the Subjects and Others

Discuss the potential benefits of the research to the subjects and others. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others

4. Importance of the Knowledge to be gained

Discuss the importance of the knowledge gained or to be gained as a result of the proposed research. Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result

Inclusion of Women, Minorities, and Pediatric Populations

A separate report is needed for inclusion of women. Inclusion of ethnic and racial categories (minorities) is also a separate section. Children (< age 21) must be included unless there are clear and compelling reasons not to include them. Address each separately with the following information:

Inclusion of Women

- 1. Description of subject selection criteria** by gender and reason for this selection in terms of scientific objectives and study design. NIH requires that women be included in all GCRC protocols. At minimum, inclusion of women should match their representation in the Kansas population (see www.census.gov)
- 2. Compelling rationale for proposed exclusion** of any sex/gender
- 3. Description of proposed outreach programs for recruiting women** in clinical research as subjects

Inclusion of Minorities

- 1. Description of subject selection criteria** by ethnic and racial categories and reason for this selection in terms of scientific objectives and study design. NIH requires that minorities be included in all GCRC protocols. At the very least, inclusion of minorities should match their representation in the Kansas population (www.census.gov)
- 2. Compelling rationale for proposed exclusion** of any ethnic or racial group
- 3. Description of proposed outreach programs for recruiting minorities** in clinical research as subjects

Inclusion of Children (less than age 21)

- 1. Description of subject selection criteria** by age and rationale for this selection in terms of scientific objectives and study design. NIH requires that children be included in all GCRC protocols, unless there are clear and compelling reasons not to include them. If children are included, the description of the plan should include a rationale for selecting or excluding a specific age range of children.
- 2. Compelling rationale for proposed exclusion** of children. Justification for exclusion of children: a) the topic is not relevant to children, b) there are laws or regulations barring the inclusion of children in the research, c) knowledge being sought in the research is already available from children or will be obtained from another ongoing study, d) a separate, age-specific study in children is warranted and preferable, e) insufficient data are available in adults to judge potential risk in children, f) study designs aimed at collecting additional data on pre-enrolled adult study subjects (longitudinal follow-up studies that did not include data on children), g) other special cases justified by the investigator and found to be acceptable to the review group and the Institute Director.
- 3. Description of expertise of the investigative team** for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

Sample composition tables (required)

The following enrollment planning and reporting tables regarding race and ethnicity must be completed. For this purpose the ethnic and race categories used are considered social-political constructs and anthropological in nature. Each patient should be identified by ethnicity and race. The categories used in both of the following tables match the categories in the 2000 US Census. The following definitions from OMB Directive 15 apply for the ethnic and racial categories:

Ethnic Categories:

Hispanic or Latino – A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.

Not Hispanic or Latino

Racial Categories:

American Indian or Alaska Native – A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.

Asian – A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for examples, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Phillipine Islands, Thailand, and Vietnam. (Note: Individuals from the Phillipine Islands have been recorded as Pacific Islanders in previous data collection strategies)

Black or African American – A person having origins in any of the black racial groups of Africa.

Native Hawaiian or Other Pacific Islander – A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands

White – A person having origins in any of the original peoples of Europe, the Middle East, or North Africa

Targeted/Planned Enrollment Table: (required of all studies)

Study Title: insert study title which must match consent form

Total Planned Enrollment: insert number

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino			
Not Hispanic or Latino			
Ethnic Category Total of All Subjects*			
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
Racial Categories: Total of All Subjects*			

* The “Ethnic Category Total of All Subjects” must be equal to the “Racial Categories Total of All Subjects”

Inclusion Enrollment Report Table: (if you are already enrolling subjects)

Study Title: insert study title (must match consent form)

Total Enrollment: _____

Part A. TOTAL ENROLLMENT REPORT:				
Number of subjects enrolled to date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				*
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
Racial Categories: Total of All Subjects*				*

PART B. HISPANIC ENROLLMENT REPORT:				
Number of Hispanics or Latinos Enrolled to Date (Cumulative)				
Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
Racial Categories: Total of Hispanics or Latinos**				**

*These totals must agree

**These totals must agree

GCRC Needs and Requirements

Your study will utilize:

_____ Outpatients _____ Inpatients (Scatterbeds) _____ Both

Total # of patients/controls to be studied: _____

Outpatients:

	Year 1	Year 2	Year 3	Year 4	Year 5
# of outpatients					
# of visits/patient					
Total # of outpatient visits					
Average hours per visit					

Scatterbed Patients:

	Year 1	Year 2	Year 3	Year 4	Year 5
# of patients					
# of hospital days/patient					
Total # of scatterbed days					

Provide justification of proposed use of GCRC resources in detail: list all resources of the GCRC (outpatient nursing, scatterbed nursing, lab, biostatistics/data management, etc) that will be used, describe exactly what procedures GCRC staff will be performing, the number and lengths of visits to be done at the GCRC or off site by GCRC staff, describe how GCRC will supplement current or proposed funding, and explain any variations in proposed GCRC usage and the protocol as written.

Literature Cited

List only literature cited within the text. Use NIH format: name of all authors, title, book or journal, vol, page, year.

A Biographical Sketch needs to be Submitted for Project Principal Investigator and all Co-Investigators

Use PHS 398 format (go to <http://grants.nih.gov/grants/funding/phs398/phs398.html> for downloadable instructions and form files. The Biographical Sketch Format Page is under individual form files). The Biographical sketch may not exceed 4 pages. Items A and B (together) may not exceed two of the four-page limit. Biographical Sketch sample is on following four pages.

Principal Investigator/Program Director (Last, first, middle):

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.
Follow the sample format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME		POSITION TITLE		
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>				
INSTITUTION AND LOCATION		DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY

NOTE: The Biographical Sketch may not exceed four pages. Items A and B (together) may not exceed two of the four-page limit. Follow the formats and instructions on the attached sample.

A. Positions and Honors. List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.

B. Selected peer-reviewed publications (in chronological order). Do not include publications submitted or in preparation.

C. Research Support. List selected ongoing or completed (during the last three years) research projects (federal and non-federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and your role (e.g. PI, Co-Investigator, Consultant) in the research project. Do not list award amounts or percent effort in projects.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.
Follow the sample format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME		POSITION TITLE	
Carlucci, Joseph Louis		Professor of Microbiology	
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Stanford University	Ph.D.	1964	Infectious Diseases
Harvard Medical School	M.D.	1972	Medicine/Parasitology

A. Positions and Honors.**Positions and Employment**

1969-1971 Medical Residency, Internal Medicine, Harvard Medical School
 1971-1973 EIS Officer, Hospital Infection Section, Bacterial Diseases Branch, CDC, Atlanta, GA
 1973-1974 Instructor and Fellow in Medicine, Hematology, Massachusetts General Hospital, Boston, MA
 1974-1975 Instructor in Infectious Diseases, Massachusetts General Hospital, Boston, MA
 1978- Senior Associate in Infectious Diseases, Children's Hospital, Boston, MA
 1978-1984 Assistant Professor of Pediatrics, Harvard Medical School
 1985-1998 Chief, Hemostasis Laboratory, Children's Hospital, Boston, MA
 1993- Professor of Pediatrics, Harvard Medical School, Boston, MA
 1998- Professor, Dept. of Infectious Diseases, Harvard School of Public Health

Other Experience and Professional Memberships

1972-1973 Acting Chief, National Mucosal Infections Study
 1975-2000 Director of Infectious Diseases Laboratory
 1975-present Hospital Epidemiologist (Medical Director Infection Control 2000-present), Children's Hospital, Boston
 1981-1982 President, Society of Hospital Epidemiologists of America
 1988 Member, Society for Pediatric Research
 1989-present Medical Director Quality Assurance, Children's Hospital, Boston, MA
 1991-1993 Director, American Society for Microbiology, Division F
 1991-1997 Hospital Infection Control Practices Advisory Committee, Centers for Disease Control
 1998-present Vice-Chair for Health Outcomes, Dept. of Medicine, Children's Hospital
 1998-2001 Steering Committee, NACHRI/CDC Pediatric Prevention Network

Honors

1982 SERC Advanced Research Scholarship, Infectious Disease Society of America
 2001 Anthony Steinway Award for Excellence in Teaching (Children's Hospital)

B. Selected peer-reviewed publications (in chronological order).

(Publications selected from 133 peer-reviewed publications)

1. Luciani JM, Casper J, Goodman BF, Shaw CM, Carlucci JL. Prevention of respiratory virus infections through compliance with frequent hand-washing routines. *N Engl J Med* 1988 ;318:389-394.

2. Gussmann J, Pratt R, Sideway DG, Sinclair JM, Emmerson MF, Carlucci JL. Coagulase-negative staphylococcal bacteremia in the changing neonatal intensive care unit population. Is there an epidemic? *JAMA*. 1988;158:1548-1552.
3. Gussmann J, Carlucci JL, McGovern JE, Jr., Methodologic issues in nursing home epidemiology. *Rev Infect Dis* 1989;11:1119-1141.
4. Gussmann J, Emmerson MF, Smyth NE, Platt RI, Sidebottom DG, Carlucci JL. Early hospital release and antibiotic usage with nosocomial staphylococcal bacteremia in two neonatal intensive care unit populations. *Amer J Dis Child* 1991;149:325-339.
5. Murphy JA, Black RW, Schroeder LC, Weissman ST, Gussman JM, Carlucci JL, Short CJ. Quality of care for children with asthma: the role of social factors and practice setting. *Pediatrics* 1996;98:379-84.
6. Gussmann J, Carlucci JL, McGovern JE, Jr. Incidence of *Staphylococcus epidermidis* catheter-related bacteremia by infusions. *J Infect Dis* 1996;172:320-4.
7. Carlucci JL, Huskins WC. Control of nosocomial antimicrobial-resistant bacteria A strategic priority for hospitals worldwide. *Clin Infect Dis* 1997;S139-S145.
8. Corning WC, Saylor BM, O'Steen C, Gulapagos L, O'Reilly EJ, Carlucci JL. Hospital infection prevention and control: A model for improving the quality of hospital care in low income countries. *Infect Control Hosp Epi*. 1999;13:123-35.
9. Handler CJ, Marriott B, Clearwater PT, Carlucci JL. Quality of care at a children's hospital: the child's perspective. *Arch Pediatr Adolesc Med*. 1999;143:1120-7.
10. McKinney D, Poulet KL, Wong Y, Murphy V, Ulright M, Dorling G, Long JC, Carlucci JL, Piper GB. Protective vaccine for *Staphylococcus aureus*. *Science* 1999;214:1421-7.
11. Gulazzii L, Kispert ZT, Carlucci JL, Corning WC. Risk-adjusted mortality rates in surgery: a model for outcome measurement in hospitals developing new quality improvement programs. *J Hosp Infect* 2000;24:33-42.
12. Huebner J, Qui A, Krueger WA, Carlucci JL, Pier GB. Prophylactic and therapeutic efficacy of antibodies to a capsular polysaccharide shared among vancomycin-sensitive and resistant enterococci. *Infect Immun* 2000; 68:4631-6.
13. Levitan O, Sissy RB, Kenney J, Buchwald E, Maccharone AB, Carlucci JL. Enhancement of neonatal innate defense: Effects of adding a recombinant fragment of bactericidal protein on growth and tumor necrosis factor-inducing activity of gram-positive bacteria tested in vivo. *Immun* 2000;38:3120-25.
14. Garletti JS, Harrison MC, Collin PA, Miller CD, Otter D, Shaker C, Wren M, Carlucci JL, Makato DG. A randomized trial comparing iodine to a alcohol impregnated dressing for prevention of catheter infections in neonates. *Pediatrics*. 2001;127:1461-6.
15. Corning WC, Barillo K, Festival MR, Lingonberry S, Lumbar P, Peters A, Pursons M, Carlucci JL, Tella JE. A national survey of practice variation in the use of antibiotic prophylaxis in heart surgery. *J Hosp Infect*. 2001;33:121-5.
16. Hoboken S, Peterson D, Graveldy L, Carlucci JL. Compliance with hand hygiene practice in pediatric intensive care. *Pediatric Crit Care Med*. 2001;12:211-214.
17. Hasker S, Pittoui D, Gray L, Zaruccii A, Potter G, Seemore MH, Carlucci JL. Interventional study to evaluate the impact of an antibiotic-infused hand gel in improving hand hygiene compliance. *Pediatr Infect Dis J*. Accepted for publication.
18. Lander C, Summers R, Murray S, Hummer CJ, Carlucci JL. Pediatrics: Is hospital food more nutritional than mom's cooking? *Pediatrics* 2001;11: 140-145.

C. Research Support

Ongoing Research Support

R01 HS35793 Carlucci (PI)

9/01/99-8/30/04

AHRQ

Reducing Antimicrobial Resistance in Low-Income Communities: A Randomized Trial.

This study is a randomized trial of interventions to reduce antimicrobial usage and resistance in low-income communities.

Role: PI

Ongoing Research Support (cont.)

2 R01 AI12345-05 Carlucci (PI) 4/01/01-3/31/06
NIH/NIAID
Bacteriology and Mycology Study of ICU Patients at Risk for Antimicrobial Resistant Bacterial Infections.
The study will perform clinical trials of interventions to reduce antimicrobial resistant infections.
Role: PI

R01- AI24680-04 Peterson (PI) 3/01/01-2/28/06
NIH/NIAID
Virulence and Immunity to Staphylococci.
This study investigates the production of polysaccharide by *Staphylococcus aureus* and its role in virulence as measured in animal models of infection and its ability to function as a target for protective antibody.
Role: Paid consultant.

2 R01 HL 00000-13 Anderson (PI) 3/01/01-2/28/06
NIH/NHLBI
Chloride and Sodium Transport in Airway Epithelial Cells
The major goals of this project are to define the biochemistry of chloride and sodium transport in airway epithelial cells and clone the gene(s) involved in transport.
Role: Co-Investigator

5 R01 HL 00000-07 Baker (PI) 4/1/01 – 3/31/04
NIH/NHLBI
Ion Transport in Lungs
The major goal of this project is to study chloride and sodium transport in normal and diseased lungs.
Role: Co-Investigator

1 R01 AI12826-01 Hoffman (PI) 9/28/01-9/27/03
NIH/NIAID
Intermountain Child Health Services Research Consortium
This consortium will seek to build pediatric health services research capacity and training in the Intermountain Region.
Role: Co-Investigator

Completed Research Support

5 RO1 AI10011-05 Herman (PI) 10/01/99 – 11/30/01
NIH/NIAID
Evaluating Quality Improvement Strategies (EQUIS)
The goal of this study was to evaluate quality improvement and collaborative learning to improve asthma care in office-based pediatrics.
Role: Co-Investigator

5 R01 AI098765 Spielman (PI) 7/01/96 -6/30/01
NIH/NIAID
Epidemiology of Emerging Infections #1 T32 AI07654
The goal of this project was to study emerging infections in high risk populations who are treated in emergency room situations.
Role: Co-Investigator

Appendix 1

GCRC Study Subject Categories

Participants in research protocols conducted on the GCRC are allocated to a patient category based on the reporting requirements of the NIH. These assignments are made prospectively for each research study by the GCRC Advisory Committee, in consultation with the primary investigator.

Category A – Research Patients: These are research inpatient days or outpatient visits utilized solely for research purposes. All outpatient visits and or hospitalization costs associated with category A days are the responsibility of the GCRC or an investigator's research funds. Neither the patient nor their third party carrier can be billed for research related charges.

Category B – Research Service Patients: This category includes patients who require hospitalization or outpatient visits for diagnosis or treatment, and in addition, are on an investigator designed research protocol. The cost of established medical care for the patients is not charged to the GCRC. The patient or third party carrier is responsible for the costs which relate to non-research charges. The costs of those ancillary services performed solely for research on Category B patients and not related to their routine medical care may be charged to the GCRC.

Category C – Non-research patients: Not applicable @ KUMC

Category D – Industry –Initiated Projects: 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. There are nursing and laboratory charges for these studies.

It is essential that the presence of category D and C patients not compromise other research activities involving categories A and B patients on the GCRC. At this time, we expect no category C studies and a limited number of category D studies would occur in the GCRC at KUMC.

Note: Above summarized from the General Guidelines for the General Clinical Research Centers Program updated March 2004.

Appendix 2
University of Kansas Medical Center GCRC
Protection of Human Subjects Checklist

This checklist should assist you in formulating the written data and safety monitoring plan required in the protocol.

Protocol Title:

1. Training -

- Verify all research personnel have completed all **appropriate and required** KUMC training:
 - KUMC Human Subjects Protection (enclose certificate)
 - HIPAA (enclose certificate)
 - Safety (enclose certificate)
 - Conflict of Interest Disclosure
- Verify all research personnel have completed NIH course, Human Participant Protections Education for Research Teams, located at <http://cme.nci.nih.gov> (This is a NIH requirement for investigators who apply for or receive NIH funding for research involving people.)

2. Risk Categorization – Please choose the appropriate level of risk associated with this study and use the space provided to justify the risk level associated with this study.

Minimal Risk

- intravenous catheter insertion
- oral glucose tolerance tests
- intravenous glucose tolerance tests
- DEXA scans
- MRI scans
- special diets
- exercise testing
- EKG's
- anthropomorphic evaluations

- Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required.
- Prospective collection of biological specimens for research purposes by noninvasive means.
- Collection of blood samples by finger stick or venipuncture as follows:
 - from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week;
 - from other adults and children¹, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.
- Other: Please describe:

¹ Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).

Moderate Risk

This study has moderate levels of risks associated with (check all that apply):

research associated procedures of undefined risk or with a low frequency of serious adverse events (specify)

interventions of undefined risk or with a low frequency of serious adverse events (specify)

study drugs

Other: Please describe:

The study has a low or moderate level of risk in (check all that apply):

vulnerable populations

populations at risk for serious clinical events based on underlying disease

High Risk

This study has high levels of risk associated with (check all that apply):

use of high risk drugs

use of high risk procedures (specify): _____

use of interventions associated with the risk of serious adverse events at high or uncertain frequency

is a gene transfer/gene therapy study

The study involves:

Populations associated with very high risk of serious adverse clinical events based on underlying disease or in whom assessment of treatment-associated adverse events may be difficult.

Other: Please describe:

3. Monitoring and Safety Review

a. **Who will monitor?** (Identify the monitor(s)/reviewer(s), qualifications, potential financial conflicts of interest and contact information)

b. **What will be monitored?**

- Number of subjects screened and enrolled. Yes No
- Drop-outs. Yes No
- Primary and secondary efficacy endpoints Yes No
- Adverse Events (serious and nonserious) using an accepted scale. Yes No

Please identify the scale for categorization and classification of adverse events:

CTC II (see <http://ctep.info.nih.gov> "Reporting Guidelines, Common Toxicity Criteria")

WHO scale

Other: _____

c. How frequently will data be monitored and reported?

- Every 12 months (coincides with HSC periodic review)
- Every 6 months
- Every 3 months
- Other: Please describe:

d. What are the plans for interim analysis?

- None
- Other: Please describe: