Children's Hospital of Pittsburgh
Pediatric and Clinical translational Research Center (PCTRC)
Application Guidelines

SECTION I:

I. PROTOCOL FORMAT (IRB Format is Acceptable - Please Include sections J and K Below)

The protocol should be clearly written in narrative form, including the following information, section A-L. There is no page limit, but the proposal should be complete enough to convey all needed information to allow for an adequate review. Protocols should be hypothesis driven, and should be designed in such a manner that the work will result in publishable data, or will lead to other publishable studies. **All protocols require final IRB approval prior to PCTRC approval.**

A. Principal Investigator/Co-Investigator(s)

B. Protocol Title

C. Hypothesis and Specific Aims

State clearly the hypothesis to be tested or specific data which are sought. Long term goals of the project may be included, but do not substitute them for specific aims to be achieved by the proposed study.

D. Background Information and Significance

This section should present a convincing rationale for conducting the study. Provide background data which support the scientific importance of the proposed studies, including references. Explain how the proposed studies will add significant information to the area. This section is particularly important for pilot studies.

E. Progress Report and Preliminary Studies

Describe the results and implications of any related work that you have already accomplished. Include preliminary data that support the hypothesis or your experimental approach.

F. Research Design and Methods

Describe the research design and the procedures to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted. 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. As part of this section, provide a tentative sequence or timetable for the project. Identify any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

G. Biostatistical Design and Analysis

Describe the measurements that will be made and the calculations that will be carried out. Include the description of statistical methods with which the data will be analyzed. Include sample size and power estimates.

A small pilot study may not result in statistically significant data. However, in order to help the Advisory Committee determine the study's scientific validity, explain how data will be evaluated. Explain exactly what you will be measuring and what changes you expect, and what factors will be involved in a decision to move onto a larger study.

The PCTRC biostatistician, Dr. Janine Janosky is available to assist investigators in the development of the statistical methodology and power analysis. Dr. Janosky's office is located in 3518 Fifth Avenue, Department of Family Medicine and Clinical Epidemiology. Her phone number is 412-383-2359.

H. Human Subjects

The NIH requires that the following six areas be addressed in all PCTRC protocols. Please number the paragraphs 1-6.

1. Subject Population: Describe the characteristics of the subject population, including their anticipated number, age ranges, gender, racial/ethnic background, and health status. Explain the rationale for the involvement of special classes of subjects, if any, such as fetuses, pregnant women, children, or others who are likely to be vulnerable. Identify the criteria for inclusion and exclusion. If one gender and/or minorities are excluded or are inadequately represented in this research, particularly in proposed population-based studies, a clear compelling rationale for exclusion or inadequate representation should be provided. It is the NIH policy that children (individuals under the age of 21) must be included in all human subjects' research, unless there are clear and compelling reasons not to include them.

2. Source of Research Materials: Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

3. Recruitment Methods: Describe plans for the recruitment of subjects and the consent procedures to be followed, including the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. State if the Institutional Review Board (IRB) has authorized a modification or waiver of the elements of consent or the requirement for documentation of consent.

4. Potential Risks: Describe the potential risks (physical, psychological, social, legal or other) and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

5. Risk Management Procedures: Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects.

6. Evaluation of the Risk/Benefit Ratio: Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

I. Data Safety and Monitoring Plan

In order to comply with federal regulations and ensure the protection of research subjects, the PCTRC requires a Data Safety and Monitoring Plan (DSMP) in all protocols submitted for PCTRC support. Renewals must also contain updated protocol summaries that also include DSMP information. The DSMP should address all of the following:

1. Who will oversee and assume responsibility for monitoring
2. Specific parameters that will be monitored
3. Details of plans for compliance with SAE reporting requirements **to both IRB and PCTRC**

4. The frequency of monitoring
5. Plans for submission (frequency) of DSMP reports to the **IRB and PCTRC**

For those projects where the major risk to subjects is breach of confidentiality, the DSMP should focus on the oversight of privacy issues.

J. Justification for Utilization of PCTRC Resources

A detailed explanation is required as to why the PCTRC is necessary and appropriate for this study. State all PCTRC resources you intend to use (inpatient, outpatient, ancillary support required, off site nursing etc.) and justify the need for each.

K. Study Size and PCTRC Resources

1. Number of Research Subjects
2. Annual Number of Research Patient Days
3. Annual Number of Outpatient Visits and Length of Visit

L. References

Support your hypothesis and methodology with appropriate references, numbered in order of citation. This should include publications resulting from prior research in this area performed by yourself or others.

SECTION II. IRB CONSENT

All PCTRC protocols must have ongoing approval by the Institutional Review Board (IRB). A copy of the IRB approval must be included in the protocol application for review by the PCTRC Advisory Committee. It is the responsibility of the investigator to assure that IRB approval remains current throughout the duration of long-term projects.

SECTION III. APPLICATION/BUDGET FORMS

Please use the accompanying application and complete all sections. Much of the information requested is transferred into the NIH database in accordance with NIH program guidelines. The application must be signed by the Principal Investigator. Submit only the original application including the budget pages, complete protocol, consent form and IRB approval for your project.

The PCTRC staff can provide valuable assistance in preparing a proposal. Please do not hesitate to contact the following individuals for information and advice regarding preparation of your proposal.

Silva Arslanian, M.D.	Director	692-6565
Patrick M. Kochanek, M.D.	Associate Director	383-1901
P. David Adelson, M.D.	Associate Director	692-6347
Lynnette Orlansky	Administrative Director	692-5573
Janet Bell, R.N.	Nurse Manager	692-6327
Janine Janosky, Ph.D.	Biostatistician	383-2359
Michael Green, M.D., M.P.H.	Research Subject Advocate	692-6111

Budget Classification/PCTRC Resources

The extent to which the PCTRC can fund the costs of hospitalization and testing for your study depends upon a categorization of the study's inpatient and outpatient activity. The categories are as follows:

Category A - Research only (patients admitted for research purposes only). All testing is research and covered by research funds.

Category B - Research/service (patients admitted for both research and routine diagnostic/therapeutic purposes). Testing is covered by a third party payer.

Category D - Industry-initiated (patients participating in industry-sponsored research). All costs associated with the project are the responsibility of the industrial sponsor.

The PCTRC grant will cover the cost of hospitalization and approved research tests for category A patients. It also pays for research-related tests on category B patients, but does not cover the costs of the hospital room charges, clinic visits or non-research charges. Charges for category D patients are the responsibility of the drug company-industrial sponsor. **Patients who meet the Category B classification criteria <u>may not</u> be classified as Category A simply because they lack applicable insurance.**

Complete the budget pages identifying your request for inpatient and outpatient support on the corresponding pages. It is not necessary to complete the charges for the specific research test unless they are preformed outside of Children's Hospital; this section will be completed by the PCTRC manager. The PCTRC cannot support costs related to salary support, professional fees, subject recruitment, or parking fees. Investigators are strongly advised to discuss the budget with the manager prior to submission of the PCTRC application.

DEXA Scans

The Pediatric PCTRC offers services of a GE Lunar Advanced Prodigy DEXA Scanner to PCTRC investigators for both inpatient and outpatient protocols. The DEXA scanner is located on the outpatient PCTRC unit; services are provided by the PCTRC staff. There is no charge for scans, unless the research study is industry initiated.

SECTION IV. REVIEW PROCESS

Protocol Approval

The PCTRC Advisory Committee typically meets monthly to review project proposals. Please contact the administrative office 412-692-5746 for a complete schedule of the meeting dates. Proposals must be received in the PCTRC administrative office (Room 8505 MT) on the first working day of the month in order to be reviewed at that month's Advisory Committee meeting. The PCTRC Advisory Committee will review all protocols for scientific merit, patient safety, statistical power, study design, and budget requirements. Each application will be assigned two reviewers. Consent forms will also be reviewed to ascertain consistency and adequacy of details including study design, risks and benefits.

Proposals will be returned with approval, disapproval and/or contingencies. The PCTRC will attempt to accommodate all users; however priority scores are assigned in the event that bed space, nursing time or finances are limited. In general, first priority will be given to investigators whose projects are funded by the NIH.

Expedited Approval

The Advisory Committee Chairperson and the Program Director may provide immediate expedited approval for activation of a protocol with a limited number of patients (no more than 10% of proposed patient accrual or 3 patients) prior to final full approval providing IRB approval has been obtained. A decision of the full committee will be final.

SECTION V. INVESTIGATOR RESPONSIBILITIES

A. Annual Renewal of Proposals

All PCTRC studies require annual renewal for continued support by the PCTRC. Investigators will be notified by the PCTRC administrative office approximately 45 days prior to the required renewal. Any project more than 30 days overdue will be suspended from PCTRC support until renewal is obtained. All studies must maintain current IRB approval; studies will be suspended immediately if IRB approval is lapsed. **There will be no exceptions**.

B. Citing PCTRC Support on Publications

Our sponsoring agency, the NIH National Center for Research Resources, has requested that any publication resulting from studies conducted on the PCTRC carry the following acknowledgement:

> **"This investigation was supported in part by PHS research grant # UL1 RR024153 through the PCTRC at the Children's Hospital of Pittsburgh"**

Citing the above PCTRC grant number in your publications has an impact on continued NIH support of the PCTRC here at the Children's Hospital of Pittsburgh. We ask that you give special attention to this matter as this information is reported to the NIH annually.

C. PCTRC Reporting Policies

The PCTRC must submit an annual progress report to the NIH. This report includes a detailed listing of all active projects, their utilization of PCTRC resources, demographic data on subject population; publications generated during the grant year for PCTRC supported research, and documentation of other support for all principal investigators and co-investigators. You will receive a request for this information each January, investigators' thorough and prompt response to this yearly request will help assure continued NIH support for the PCTRC.

APPENDIX I
DRUG COMPANY FUNDED STUDIES

Drug-company funded studies can be either investigator-initiated or industry-initiated. If your proposed study is supported by industry (e.g. pharmaceutical company), indicate whether this proposal is investigator-initiated or industry-initiated. Detail your participation in the protocol design in the Research Design and Methods section.

I. INVESTIGATOR-INITIATED STUDIES

Investigator-initiated protocols, inpatient days and outpatient visits are recorded as type "A". A copy of both the agreement (contract) between you and the company and the sponsor-approved budget must accompany this application.

II. INDUSTRY-INITIATED STUDIES

In industry-initiated protocols, the company is expected to pay the **entire** patient costs. All inpatient days and outpatient visits are recorded as type "D". The company is charged for all PCTRC resources used, including inpatient days and outpatient visits. A one-time PCTRC administrative fee of $250 is charged to the company for administrative processing, budget preparation and nurse management of the protocol. The fee schedule below is charged for outpatient "D" visits. Any industry supported protocol conducted off the PCTRC unit requiring sample collection will be charged on a per sample basis. Investigators are strongly encouraged to consult with the PCTRC when preparing the industry supported budget. PCTRC research rates are only applicable for industry initiated studies once approved by the PCTRC Advisory Committee. Copies of both the contract with the drug company and the official protocol must accompany the application. Principal investigators must also complete the required forms to establish a CHP research account through the Research Administration Office prior to initiation on the PCTRC.

Outpatient PCTRC Fee Schedule for "D" Protocols

Hours	Fee
0 - 1	$ 45.00
1 - 2	$ 75.00
2 - 3	$105.00

An additional $30.00/hour charge over 3 hours.

Specimen collection and processing fee for off-unit protocols is $15.00/specimens.

DEXA Scans rate for industry studies is $125