PEDIATRIC CLINICAL AND TRANSLATIONAL RESEARCH CENTER
General Application Procedures

- **Institutional Review Board (IRB):** As of 2/1/07, scientific review is required before submitting your new protocol to the IRB. However, final approval to begin your study with the PCTRC will not be granted until final IRB approval is obtained; the PCTRC requires the IRB approval letter, protocol and consent documents.
- **Preparation of Application:** The PCTRC Directors and Administrator are available for assistance in planning your protocol application. You are encouraged to discuss your application with the PCTRC before the final copy is prepared. Please review the Application Guidelines available online.
- **Outside Resources:** Investigators are encouraged to use PCTRC resources in conjunction with grant applications for clinical research from outside sources --especially the National Institutes of Health.
- **Review Process:** All protocols must be approved by the PCTRC Advisory Committee which meets monthly. Protocols are reviewed for scientific merit, need for PCTRC resources, biostatistical design and adequacy of consent forms. Each protocol is reviewed by two committee members, the PCTRC Research Subject Advocate and the PCTRC Biostatistician each of who submit a written evaluation of the study for discussion at the monthly committee meeting. The members of the committee vote to approve, disapprove, or defer consideration. Each committee member also assigns a "Scientific Merit" and "Need for Center" priority score for each protocol. These priority scores use the NIH evaluation system 1.0 (highest) - 5.0 (lowest). The scores are used to determine priority for scheduling among the approved protocols. All investigators will be notified of the committee's decision by letter.
- **Approved Protocols:** After approval of a protocol, the investigator must contact the PCTRC Nurse Manager to arrange a meeting in order to familiarize them with the mechanics of the protocol.
- **Publications:** It is important that all publications resulting from studies conducted using PCTRC resources credit the PCTRC NIH Grant # **UL1 RR024153**.

CHECKLIST FOR SUBMITTING A RESEARCH STUDY FOR USE ON THE PCTRC

☐ 1. Completed and signed PCTRC Application Form

☐ 2. Narrative Summary in NIH/IRB format as outlined in the instructions
(This should be the IRB approved protocol with the PCTRC sections added)

☐ 3. Copy of IRB Approval Letter

☐ 4. Approved Consent Form(s) - consent forms must be IRB approved and dated

☐ 5. Completed Inpatient and/or Outpatient Budget Forms

☐ 6. Send completed application electronically to: lynnette.orlansky@chp.edu. Send 1 hard copy of entire package to PCTRC Office.

Please be sure to answer ALL questions on the attached forms. Please pay particular attention to the number of patients to be studied, the type of patient (inpatient/outpatient, "A"-grant, "B"-third party, "D"-industry supported) and the tests to be performed. You are encouraged to discuss your budget with the PCTRC Administrator, Lynnette Orlansky before the application is submitted (412- 692-5573).

PEDIATRIC CLINICAL AND TRANSLATIONAL RESEARCH CENTER

Children's Hospital of Pittsburgh

NEW APPLICATION

The objective of the Pediatric Clinical and Translational Research Center Program is to make available to medical scientists the resources which are necessary for the conduct of clinical research. The primary purpose of the PCTRC is to provide the clinical research infrastructure to investigators who receive their primary research funding from other components of the NIH and to encourage collaboration among basic and clinical scientists through studies that may translate into new or improved patient care methods.

Date Submitted: _____

Protocol Title: _____

Principal Investigator: _____

Name Degree(s) E-mail address

Academic Appointment/Position Department Division

Campus Address Telephone #

Contact for PI: (Study Coordinator, Study Nurse, Admin. Asst., etc)

Name Telephone # E-mail address

Co-Investigator(s):

Name, Degree(s) and Academic Appointment Department Telephone #

Institutional Review Board (IRB) Approval, *if applicable* ***

☐ Approved (attach copy of IRB approval letter) Date Approved: _____

*****Please Note: As of 2/1/07, all new pediatric protocols must receive Scientific Review before IRB approval is granted**

Signature of Principal Investigator Who Will Be Responsible for Medical Care of Subjects **Date**

Start Date: **Anticipated End Date of Study:**

Total Number of Patients Expected for Entire Study at CHP:

Total Number of Patients Expected at CHP during your first year:

Please Check the Appropriate Boxes:

Is this a Multi-center Study? ☐ Yes ☐ No **If yes, please attach the Multi-center Protocol.**

Type of Study: ☐ Inpatient ☐ Outpatient ☐ Both

Type of Research: ☐ Clinical Research ☐ Clinical Trial If Clinical Trial, Which Phase* I, II, III, IV Please see Addendum for definitions*

Other Sources of Support for this study only: ☐ NONE

☐ NIH Grant # Funding Period: To

☐ Foundation Grant # Funding Period: To

☐ Industry Sponsor Funding Period: To
If industry supported, is the study
☐ Investigator Initiated or ☐ Industry Initiated CHP Account #

☐ Other Funding:

Please provide a brief abstract of the study. This information is transferred into the NIH database.

Please describe how the PCTRC can facilitate the goals of the research proposal.

ADDENDUM* FOR PCTRC NEW APPLICATION

(Please do not include this page when you submit your application.)

The following definitions of clinical research and clinical trials were developed by the Office of the Director of the NIH, after reviewing materials from the NIH Panel on Clinical Research and a review of materials in the National Library of Medicine.

CLINICAL RESEARCH:

Clinical research is research conducted with human subjects or on material of human origin, such as tissues, specimens, or cognitive phenomena, in which an investigator interacts directly with human subjects. It may include development of new diagnostic, prophylactic, or therapeutic technologies, human disease mechanisms, clinical trials, epidemiologic, behavioral, outcome and health services research.

CLINICAL TRIALS:

Clinical trials are prospective studies in human subjects designed to assess the safety, efficacy, and value of one or more interventions against a control. These new drugs, devices, treatments, preventive measures, or techniques are selected according to predetermined criteria of eligibility and observed for predefined evidence of effects or outcome.

Your study should be classified according to the following definitions: **Please note, you may indicate that your study is between two classifications. Please define: I, I-II, II, II-III, III, III-IV, or IV**

Clinical trial phase I studies are performed to evaluate the safety of diagnostic, therapeutic, or prophylactic drugs, devices, procedures, or techniques in healthy volunteer subjects or in patients. These tests are used to determine pharmacologic and pharmacokinetic properties, structure/activity relationships, safe dosage range, toxicity, metabolism, absorption, elimination, preferred route of administration, and involve a small number of persons.

Clinical trial phase II studies are well controlled and closely monitored clinical studies to evaluate the safety, efficacy, or optimum dosage schedule of one or more diagnostic, therapeutic, or prophylactic drugs, devices, or techniques. These studies are conducted with a relatively small number of patients, involving no more than several hundred subjects.

Clinical trial phase III studies are expanded studies performed after preliminary evidence suggesting effectiveness has been obtained. They are performed on patient groups closely monitored by physicians that are large enough, from several hundred to several thousand, to identify clinically significant responses.

Clinical trial phase IV studies are planned post-marketing clinical studies of diagnostic, therapeutic, or prophylactic drugs, devices, or techniques that have been approved for general sale. These studies are often conducted to obtain additional data about the safety and efficacy of a product.