
PEDIATRIC CLINICAL AND TRANSLATIONAL RESEARCH CENTER

Children's Hospital of Pittsburgh

Application to Use the PCTRC

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: _____ Type of Application: Revised Application
 Annual Renewal

PCTRC Study No: _____

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***

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

***Please Note: IRB approval must be obtained prior to submitting your application to the PCTRC for renewal or modification.

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

Date

Briefly summarize the objectives of the study. Indicate any changes in research design since the last date of PCTRC approval. Attach one copy of the complete protocol and consent form(s) to this application.

The following information is reported to the NIH annually. Each section must be completed in its entirety. Incomplete applications will be returned.

Please Check the Appropriate Boxes:

Type of Study: Inpatient Outpatient Both

Other Sources of Support for this study only:

None

| | | | |
|-------------------------------------|-------------------|-----------------------|----------|
| <input type="checkbox"/> NIH | NIH Grant # _____ | Funding Period: _____ | To _____ |
| <input type="checkbox"/> Foundation | Grant # _____ | Funding Period: _____ | To _____ |
| <input type="checkbox"/> Industry | Sponsor _____ | Funding Period: _____ | To _____ |

If industry supported, is the study

Investigator Initiated or Industry Initiated

CHP Account # _____

Other Funding: _____

Original

Start Date: _____ Anticipated End Date of Study: _____

Total No. of Patients Expected for Entire Study at this site (CHP): _____

Total No. of Patients Expected for Entire Multicenter Study: _____

Total No. of Patients Studied to date for Entire Multicenter Study : _____

Total No. of Patients Studied to date at this site (CHP): _____

Total No. of Patients Studied during your past yr with the PCTRC: _____

Please Check the Current Status of the Study:

Active subject recruitment and enrollment; patient studies ongoing.

Enrollment completed; patient studies ongoing

Patient studies are complete; data analysis ongoing.

Enrollment justification for any under or over enrollment; please indicate what measures will be taken to improve any under enrollment:

Changes On The Consent Form Since Last Approval Date: YES NO

Serious Adverse Events During this 12 Month Reporting Period: YES NO

If YES, were all of these serious adverse events reported to the PCTRC YES NO

If not reported, indicate what precautions have been developed to prevent this type of protocol violation in the future and include a copy of the SAE reporting form with this renewal application:

Please write a brief progress report of the activity and findings of the study to date. If PCTRC utilization is significantly above or below projected utilization for the year, please provide adequate justification. An abstract may not be substituted for the progress report. Please use additional pages if necessary.

Please list all abstracts and publications resulting from this protocol since the last date of PCTRC approval and attach a copy of each to this application.
