



## Clinical & Translational Research Center (CTRC)\* Protocol Submission Form (PSF)

This form is to request all services and costs from the CTRC

*\*formerly GCRC*

Date (submitted/revised):

Principal Investigator:

phone:

pager:

Study Coordinator:

phone:

pager:

Co-Investigators:

Title:

Estimated Study Duration: \_\_\_\_\_ months or \_\_\_\_\_ years

If Inpatient: (fill in box)

	Year 1		Year 2		Year 3		Year 4		Year 5	
	A*	B*	A	B	A	B	A	B	A	B
How many patients do you anticipate?										
How many days do you anticipate per subject?										
Total number of patient days?										

If Outpatient: (fill in box)

	Year 1		Year 2		Year 3		Year 4		Year 5	
	A*	B*	A	B	A	B	A	B	A	B
How many patients do you anticipate?										
How many visits do you anticipate per subject?										
Total number of subject visits?										

**\*Definition of A and B Patients**

- A: Strictly research (Industry sponsored studies can be supported by the CTRC if subjects have a rare disease (see below).
- B: Research superimposed on medically necessary patient care (diagnostic, treatment-oriented)

**IF Scatterbed:** (Patient is on CTRC protocol and census, but cannot be hospitalized on CTRC unit)

What unit will these patients be hospitalized? \_\_\_\_\_

How many patients do you anticipate for the 1<sup>st</sup> year? \_\_\_\_\_

How many scatterbed visits per subject? \_\_\_\_\_

Please specify the CTRC nursing needs per scatterbed visit. (Use separate page, if necessary)

**Rare disease:** A "rare disease or condition" refers to any disease or condition that either (A) affects less than 200,000 persons in the United States or (B) affects more than 200,000 persons in the United States **and** for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition can be recovered from sales in the United States of such drug or other therapeutic agent. If an investigator wants to use the CTRC for industry sponsored studies for Orphan Diseases, they must be approved on a case-by-case basis by the SAC.

**CTRC Resource Utilization:** Please check all of the following CTRC resources that you will need to implement your protocol. Also, list if you have funding for any of the services. **Descriptions of Services for the Various CTRC Resources listed below can be found at the GCRC Web Site:**

<http://www.cincinnatichildrens/go/gcrc>

- Nursing Needs:** Please contact Rebecca Harper (phone 636-8750 or [Rebecca.harper@cchmc.org](mailto:Rebecca.harper@cchmc.org)), Rachel Baker (phone 636-6905 or [Rachel.baker@cchmc.org](mailto:Rachel.baker@cchmc.org)) or Carrie Keininger (phone 636-7581 or [Carrie.keininger@cchmc.org](mailto:Carrie.keininger@cchmc.org)) to facilitate initiation and performance of your study on the CTRC.
- I will not need nursing services. Need space only.
- CTRC Sample Processing Laboratory:** Please contact Rebecca Harper (phone 636-8750 or [Rebecca.harper@cchmc.org](mailto:Rebecca.harper@cchmc.org)), Rachel Baker (phone 636-6905 or [Rachel.baker@cchmc.org](mailto:Rachel.baker@cchmc.org)) or Carrie Keininger (phone 636-7581 or [Carrie.keininger@cchmc.org](mailto:Carrie.keininger@cchmc.org))
- CTRC Bionutrition/Body Composition Core:** Please contact Suzanne Summer, Research Dietitian (phone 636-2734 or [Suzanne.Summer@cchmc.org](mailto:Suzanne.Summer@cchmc.org))  
Check any of the following that you would like to have collected or analyzed by the CTRC:
- |   |   |
|---|---|
| <input type="checkbox"/> Food Intake Analysis (Diet Records or Food Intake Questionnaire) | <input type="checkbox"/> Modified Meals/Metabolic Kitchen |
| <input type="checkbox"/> Resting Energy Expenditure                                       | <input type="checkbox"/> Anthropometric Measures          |
| <input type="checkbox"/> Weighed Calorie Counts   | <input type="checkbox"/> Nutritional Assessment           |
| <input type="checkbox"/> Patient / Family Education                                       |   |
| <input type="checkbox"/> Bioelectrical Impedance or skinfolds                             |   |
| <input type="checkbox"/> DXA scans  | <input type="checkbox"/> pQCT measurements                |
- If checked, do you have funding for these services? \_\_\_\_\_
- CTRC Biochemistry Core Laboratory:** Please contact Terrie Kenney (phone 636-2229 or [Theresa.Kenney@cchmc.org](mailto:Theresa.Kenney@cchmc.org))
- |  |  |  |   |                                    |
|--|--|--|---|------------------------------------|
| <input type="checkbox"/> Glucose                       | <input type="checkbox"/> Insulin                     | <input type="checkbox"/> Vitamin A     | <input type="checkbox"/> Vitamin D 25(OH) | <input type="checkbox"/> Vitamin E |
| <input type="checkbox"/> Cortisol                      | <input type="checkbox"/> PTH                         | <input type="checkbox"/> Prealbumin    | <input type="checkbox"/> Renin-Direct     | <input type="checkbox"/> DHEAS     |
| <input type="checkbox"/> Thyroglobulin antibodies      | <input type="checkbox"/> Thyroid Peroxidase Antibody | <input type="checkbox"/> Thyroglobulin |   |                                    |
| <input type="checkbox"/> Bone marker studies (specify) | <input type="checkbox"/> Urinary Cortisol            |  |   |                                    |
| <input type="checkbox"/> Other _____                   |  |  |   |                                    |
- Core lab is not limited to the above assays. Please contact Terrie Kenney for further details.  
If checked, do you have funding for these services? \_\_\_\_\_
- CTRC Behavioral Core:** Please contact Scott Powers, PhD (phone 636-8106 or [Scott.Powers@cchmc.org](mailto:Scott.Powers@cchmc.org))
- |  |  |
|--|--|
| <input type="checkbox"/> Neuropsychological Tests              | <input type="checkbox"/> Psychiatric Structured Interviews         |
| <input type="checkbox"/> Developmental Tests                   | <input type="checkbox"/> Behavioral Observation/ Coding Procedures |
| <input type="checkbox"/> Intellectual Tests                    | <input type="checkbox"/> Other Psychological Tests, NOS            |
| <input type="checkbox"/> Behavioral/ Psychological Inventories | <input type="checkbox"/> Other _____                               |
| <input type="checkbox"/> Quality of Life Scales                |  |
- If checked, do you have funding for these services? \_\_\_\_\_
- CTRC Vascular Core:**
- Arterial Stiffness Assessment - contact Elaine M. Urbina, M.D. (phone 636-8265,

[Elaine.Urbina@cchmc.org](mailto:Elaine.Urbina@cchmc.org))

- Pulse Wave Velocity (SphygmoCor)
- Augmentation Index (SphygmoCor)
- Brachial Artery Distensibility (DynaPulse)
- Endothelial Function Assessment - contact Elaine M. Urbina, M.D. (phone 636-8265, [Elaine.Urbina@cchmc.org](mailto:Elaine.Urbina@cchmc.org))
  - Peripheral Arterial Tonometry (EndoPAT)
  - Laser Doppler Flowmetry (PeriMed)
- Vascular Ultrasound Assessment – contact Thomas R. Kimball, M.D. (phone 636-8270, [tkimball@cchmc.org](mailto:tkimball@cchmc.org))
  - Brachial Flow Mediated Dilation (Ultrasound)
  - Carotid Intima-Media Thickness  & Stiffness (Ultrasound)

If checked, do you have funding for these services? \_\_\_\_\_

### **Non-CTRC Utilization:**

**Ancillary costs:** Use the table(s) below to request all services/tests that are required to implement your protocol, including those you are requesting CTRC financial support. If services/tests are supported by investigators' laboratory or funding, do not list the cost for the tests. If you are requesting funding from the CTRC for the test, complete the cost for the tests. (Please refer to the Research compendium found on CenterLink for prices.) Excessive requests cannot be supported. The CTRC is not a funding agency. It is designed to provide infrastructure to support patient-oriented research. If you are requesting more than \$5,000/year from the CTRC for your protocol, you must discuss your budget with Dr. Heubi (636-8046) or Amy Hartkemeyer (636-4273) to discuss your needs; additional budget justification will be required. Support for requests for ancillary costs will be provided based upon scientific priority established by the CTRC Advisory Committee at the time of review of the project. **This represents your final request for CTRC services and financial support. Any modifications will require re-review by the CTRC Advisory Committee.**

**Investigational Pharmacy:** Denise Lagory, phone 636-3016

(Investigators are encouraged to include the start-up, close-out, and dispensing fees in their grant applications)

**INPATIENTS**

**If you have multiple-year studies, please attach one of these pages for each year of ancillary support that you are requesting:**

**Year #** \_\_\_\_\_

	<b>Test</b>	<b>Financial Support for Test (CTRC (C) or Investigator (I))</b>	<b>Laboratory Performing Tests (i.e., CTRC, CCHMC Lab, Endo, Bioscience)</b>	<b>No. per patient</b>	<b>No. of patients</b>	<b>Total No. of tests</b>	<b>Cost per test * (from Research Compendium)</b>	<b>Total cost</b>
<b>Investigational Pharmacy</b>	<b>Start-up fee</b>			___	___	___	<b>\$750.00</b>	<b>\$750.00</b>
	<b>Close-out fee</b>			___	___	___	<b>\$100.00</b>	<b>\$100.00</b>
	<b>Dispensing fees</b>							
	Medications							
	Other (flushes, EMLA cream, etc.)							
	<b>Radiology</b>							
	<b>Cardiology</b>							
	<b>Laboratory</b>							
	<b>Supplies</b>							
	<b>Other</b>							

**Total cost of Ancillaries for Inpatients** \$ \_\_\_\_\_

\* If supported by investigators' laboratory or funding, do not list the cost for the tests. If you are requesting funding from the CTRC for the test, complete the cost for the tests.

**OUTPATIENTS**

If you have multiple-year studies, please attach one of these pages for each year of ancillary support that you are requesting:

Year # \_\_\_\_\_

	<b>Test</b>	<b>Financial Support for Test (CTRC) (C) or Investigator (I)</b>	<b>Laboratory Performing Tests (i.e., CTRC, CCHMC Lab, Endo, Bioscience)</b>	<b>No. per patient</b>	<b>No. of patients</b>	<b>Total No. of tests</b>	<b>Cost per test * (from Research Compendium)</b>	<b>Total cost</b>
<b>Investigational Pharmacy</b>	<b>Start-up fee</b>			—	—	—	<b>\$750.00</b>	<b>\$750.00</b>
	<b>Close-out fee</b>			—	—	—	<b>\$100.00</b>	<b>\$100.00</b>
	<b>Dispensing fees</b>							
	Medications							
	Other (flushes, EMLA cream, etc.)							
	<b>Radiology</b>							
	<b>Cardiology</b>							
	<b>Laboratory</b>							
	<b>Supplies</b>							
	<b>Other</b>							

**Total cost of Ancillaries for Outpatients** \$ \_\_\_\_\_

\* If supported by investigator’s laboratory or funding, do not list the cost for the tests. If you are requesting funding from the CTRC for the test, complete the cost for the tests.

**Financial Support for Protocol:** Must be completed; if none, so state. Indicate both pending and funded awards. If pending grant or award is not awarded, will this protocol be carried out? \_\_\_\_\_ What will be the alternative source of funding? \_\_\_\_\_ **(Provide a copy of grant application budget, award or contract, that documents funded components.)**

1.  NIH Grant/Contract No. \_\_\_\_\_  
 Total Funding Period: \_\_\_\_\_  
 Total Direct Funding: \_\_\_\_\_ Current Year Funding: \_\_\_\_\_
2.  Other Federal Agency. Source and Number \_\_\_\_\_  
 Total Funding Period: \_\_\_\_\_  
 Total Direct Funding: \_\_\_\_\_ Current Year Funding: \_\_\_\_\_
3.  Foundation/Agency Funding. Source \_\_\_\_\_  
 Total Funding Period: \_\_\_\_\_  
 Total Direct Funding: \_\_\_\_\_ Current Year Funding: \_\_\_\_\_
4.  Industry (Investigator-Initiated)  
 Source (or Company) \_\_\_\_\_  
 Are bed costs funded if applicable to this study? N/A Yes No?  
 Are ancillary costs funded? \_\_\_\_\_ (If no, explain: \_\_\_\_\_ )  
 \_\_\_\_\_ )
5.  Industry (Rare Disease/TDN)  
 Source (or Company) \_\_\_\_\_  
 Are bed costs funded if applicable to this study? N/A Yes No?  
 Are ancillary costs funded? \_\_\_\_\_ (If no, explain: \_\_\_\_\_ )  
 \_\_\_\_\_ )
6.  No Extramural Research Support for Project  
 \_\_\_\_\_ Department/Division Funds Available  
 \_\_\_\_\_ Other (Specify): \_\_\_\_\_

**If this is an industry-initiated study (and not a rare disease/TDN study), it is not appropriate to request CTRC funding. For an industry-initiated study, please contact** Rebecca Harper (phone 636-8750 or [Rebecca.harper@cchmc.org](mailto:Rebecca.harper@cchmc.org)), Rachel Baker (phone 636-6905 or [Rachel.baker@cchmc.org](mailto:Rachel.baker@cchmc.org)), or Carrie Keininger (phone 636-7581 or [carrie.keininger@cchmc.org](mailto:carrie.keininger@cchmc.org)).

**HUMAN SUBJECTS/MINORITY/GENDER ADDENDUM:** Submit an addendum addressing points listed in the CTRC Human Subjects Addendum instructions included in this submission packet. We are also providing a copy of one of Dr. Heubi's submissions as an example. If you have addressed these issues in **exactly** that manner in your protocol, please put the relevant page numbers of your protocol in the space below for ease in locating this information:

Relevant Page Numbers for Human Subjects Information: \_\_\_\_\_  
 Relevant Page Numbers for Gender/Minority Information: \_\_\_\_\_

**HUMAN SUBJECT PROTECTION**

All protocols submitted for use of the CTRC must contain a **Data and Safety Monitoring Plan**. This plan should be tailored to the potential risk to the subjects in the protocol and should be included within the body of the approved IRB protocol. For Phase 1, 2 and 3 studies, it may be appropriate to formulate a Data and Safety Monitoring Board (DSMB) comprised of individuals who will be charged with assessing unanticipated adverse events and interim analysis of data to determine whether early termination is appropriate or if subject risks are excessive and modifications in the consent process or the protocol should be considered. For additional information regarding this requirement and its implementation, we have provided a link to the guidance document on Centerlink in the ORCRA Watercooler sharepoint site: [Data and Safety Monitoring in Research](#). You may also contact Dr. Jennie Noll, CTRC Research Subject Advocate, at 636-9922 or [jennie.noll@cchmc.org](mailto:jennie.noll@cchmc.org) ) for assistance. **Please add this plan to the attached human subjects' addendum document (as requested in the instructions)**. If there are questions regarding this requirement, please contact Jennie Noll at the above contact information or James Heubi, M.D. at 636-8046 or [james.heubi@cchmc.org](mailto:james.heubi@cchmc.org).

**OTHER SUPPORT:** Do you or your co-investigators have any other support not applicable to this project? If yes, please list on a separate sheet using the guidelines listed above in "Financial Support for Proposed Project". *You may attach "OTHER SUPPORT" pages from NIH grant application, also called NIH bio sketch.*