



**The General Clinical Research Center
Protocol Submission Form (PSF)**

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

ver .1 Oct 08

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 GCRC if subjects have a rare disease (see below).
- B: Research superimposed on medically necessary patient care (diagnostic, treatment-oriented)

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

What unit will these patients be hospitalized? _____

How many patients do you anticipate for the 1st year? _____

How many scatterbed visits per subject? _____

Please specify the GCRC 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 GCRC for industry sponsored studies for Orphan Diseases, they must be approved on a case-by-case basis by the SAC.

GCRC Resource Utilization: Please check all of the following GCRC 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 GCRC 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) or Rachel Baker (phone 636-6905 or Rachel.baker@cchmc.org) to facilitate initiation and performance of your study on the GCRC.

- I will not need nursing services. Need space only.

- GCRC Sample Processing Laboratory:** Please contact Rebecca Harper (phone 636-8750 or Rebecca.harper@cchmc.org) or Rachel Baker (phone 636-6905 or Rachel.baker@cchmc.org).

- GCRC Bionutrition:** Please contact Suzanne Summer, Research Dietitian (phone 636-2734 or Suzanne.Summer@cchmc.org)

Check any of the following that you would like to have collected or analyzed by the GCRC:

- | | |
|---|---|
| <input type="checkbox"/> Food Intake Analysis (Diet Records or Food Intake Questionnaire) | |
| <input type="checkbox"/> Resting Energy Expenditure | <input type="checkbox"/> Modified Meals/Metabolic Kitchen |
| <input type="checkbox"/> Weighed Calorie Counts | <input type="checkbox"/> Anthropometric Measures |
| <input type="checkbox"/> Patient / Family Education | <input type="checkbox"/> Nutritional Assessment |
| <input type="checkbox"/> Bioelectrical Impedance or skinfolds | |

If checked, do you have funding for these services? _____

- GCRC Core Laboratory:** Please contact Terrie Kenney (phone 636-2229 or 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? _____

- GCRC Body Composition Laboratory:** Please contact Donna Buckley (phone 636-8549 or Donna.Buckley@cchmc.org)

Check any of the following that is needed for your study:

- | | |
|------------------------------------|--|
| <input type="checkbox"/> DXA scans | <input type="checkbox"/> pQCT measurements |
|------------------------------------|--|

If checked, do you have funding for these services? _____

- GCRC Behavioral Core:** Please contact Douglas Ris, Ph.D. (phone 636-4336 or Douglas.Ris@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? _____

GCRC Vascular Core:

- Arterial Stiffness Assessment - contact Elaine M. Urbina, M.D. (phone 636-8265, 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)
 - Peripheral Arterial Tonometry (EndoPAT)
 - Laser Doppler Flowmetry (PeriMed)
- Vascular Ultrasound Assessment – contact Thomas R. Kimball, M.D. (phone 636-8270, tkimball@cchmc.org)
 - Brachial Flow Mediated Dilation (Ultrasound)
 - Carotid Intima-Media Thickness & Stiffness (Ultrasound)

If checked, do you have funding for these services? _____

GCRC Biostatistical Core: Please contact Shelia Salisbury, Ph.D. (phone 636-2947 or Shelia.Salisbury@cchmc.org)

- Design
- Statistical analysis and data interpretation
- Sample size / power
- Scientific report writing

If checked, do you have funding for these services? _____

GCRC Informatics Core: Please contact Catherine McGraw (phone 636-8211 or Cathy.McGraw@cchmc.org)

- Data management consultation
- REDCap Database design
- Informatics Only:** no other resources are needed. Skip to page 6 below

If checked, do you have funding for these services? _____

Non-GCRC 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 GCRC 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 GCRC 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 GCRC 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 GCRC for your protocol, you must discuss your budget with Dr. Heubi (636-8046) or Andrea Smith (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 GCRC Scientific Advisory Committee at the time of review of the project. **This represents your final request for GCRC services and financial support. Any modifications will require re-review by the GCRC 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)

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 GCRC funding. For an industry-initiated study, please contact Rebecca Harper (phone 636-8750 or Rebecca.harper@cchmc.org) or Rachel Baker (phone 636-6905 or Rachel.baker@cchmc.org).

HUMAN SUBJECTS/MINORITY/GENDER ADDENDUM: Please submit an addendum addressing points listed in the "Gender and Minority Inclusion" and "Human Subjects" sections of the NIH grant applications. In this submission packet please find the human subjects addendum guidelines and a copy from one of Dr. Heubi's submissions to utilize as an example of how to set yours up. 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

Effective, June 1, 2001, all protocols submitted for use of the GCRC 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 low risk projects, a description of how the investigator will report unanticipated adverse events to the IRB and the GCRC may be sufficient. Additional information regarding this requirement and its implementation may be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html> or you may also contact Dr. Jennie Noll, GCRC Research Subject Advocate, at 636-9922 or 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.

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.*