



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

ver 01Sep08

When submitting an industry protocol to the GCRC please submit this completed Protocol Submission Form, and one copy each of: the Industry protocol; the IRB-submitted protocol; the IRB approval letter; the IRB-approved consent form(s), and the industry protocol budget. Send to: Becca Harper or Rachel Baker at CRC/A 3 South, MLC 5006.

Use this form to request all services from the GCRC. It is assumed that if requests for services are not included on this form, those services will be obtained from alternative sources.

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
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
How many patients do you anticipate?					
How many visits do you anticipate per subject?					
Total number of patient visits?					

IF Scatterbed: (Patient is in an Industry protocol, but cannot be hospitalized on CRC unit)

What unit will these patients be hospitalized on? _____

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)

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/gcrc>

- Nursing Needs:** contact Becca Harper (phone 636-4413 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:** contact Becca Harper (phone 636-4413 or Rebecca.Harper@cchmc.org) or Rachel Baker (phone 636-6905 or Rachel.Baker@cchmc.org);

- GCRC Bionutrition:** 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:
 - Food Intake Analysis (Diet Records or Food Intake Questionnaire)
 - Resting Energy Expenditure
 - Weighed Calorie Counts
 - Patient / Family Education
 - Bioelectrical Impedance or skinfolds
 - Modified Meals/Metabolic Kitchen
 - Anthropometric Measures
 - Nutritional Assessment
 - If checked, do you have funding for these services? _____

- GCRC Core Laboratory:** contact Terrie Kenney (phone 636-2229 or Theresa.Kenney@cchmc.org)
 - Glucose Insulin Vitamin A Vitamin D 25(OH) Vitamin E
 - Cortisol PTH Prealbumin Renin-Direct DHEAS
 - Thyroglobulin antibodies Thyroid Peroxidase Antibody Thyroglobulin
 - Bone marker studies (specify) Urinary Cortisol
 - 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:** contact Donna Buckley (phone 636-8549 or Donna.Buckley@cchmc.org)
 - Check any of the following that is needed for your study:
 - DXA scans
 - pQCT measurements
 - If checked, do you have funding for these services? _____

- GCRC Behavioral Core:** contact Douglas Ris, Ph.D. (phone 636-4336 or Douglas.Ris@cchmc.org)
 - Neuropsychological Tests
 - Developmental Tests
 - Intellectual Tests
 - Behavioral/ Psychological Inventories
 - Quality of Life Scales
 - Psychiatric Structured Interviews
 - Behavioral Observation/ Coding Procedures
 - Other Psychological Tests, NOS
 - Other _____

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

- GCRC Biostatistical Core:** contact Shelia Salisbury, Ph.D. (phone 636-3430 or Shelia.Salisbury@cchmc.org)
 - Design
 - Sample size / power
 - Statistical analysis and data interpretation
 - Scientific report writing

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

- GCRC Informatics Core:** contact Catherine McGraw (phone 636-8211 or Cathy.McGraw@cchmc.org)
 - Data management consultation
 - REDCap Database design

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

Non-GCRC Utilization:

Investigational Pharmacy: Denise Lagory, phone 636-3016

(Investigators are encouraged to include the start-up, close-out, and dispensing fees in their budget to the industry company.)

Financial support for protocol: (Provide a copy of industry budget.)

Source (or Company) _____

Are bed costs funded if applicable to this study? N/A Yes No

Are ancillary costs funded? _____ If no, explain:

Name and contact information of department's administrator: _____