



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

*\*Formerly GCRC*

When submitting an industry protocol to the CTRC, 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, Rachel Baker or Carrie Keininger at CTRC/A3South, MLC 5006.

Use this form to request all services from the CTRC. 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 CTRC unit)

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

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)

**CTRC Resource Utilization:** Please check all of the following CTRC resources that you will need to implement your protocol. Also, please 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/gcrc>

- Nursing Needs:** Contact Becca Harper (phone 636-4413 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:** Contact Becca Harper (phone 636-4413 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:** 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:
    - 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? \_\_\_\_\_
- CTRC Core Laboratory:** contact Terrie Kenney (phone 636-2229 or [Theresa.Kenney@cchmc.org](mailto: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? \_\_\_\_\_
- CTRC Body Composition Laboratory:** contact Donna Buckley (phone 636-8549 or [Donna.Buckley@cchmc.org](mailto: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? \_\_\_\_\_

- CTRC Behavioral Core:** contact Scott Powers, Ph.D. (phone 636-8106 or [Scott.Powers@cchmc.org](mailto:Scott.Powers@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? \_\_\_\_\_
  
- CTRC Biostatistical Core:** contact Shelia Salisbury, Ph.D. (phone 636-3430 or [Shelia.Salisbury@cchmc.org](mailto: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? \_\_\_\_\_
  
- CTRC Informatics Core:** contact Catherine McGraw (phone 636-8211 or [Cathy.McGraw@cchmc.org](mailto:Cathy.McGraw@cchmc.org))
  - Data management consultation
  - REDCap Database design

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

**Non-CTRC 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: \_\_\_\_\_