



APPENDIX A
(Only For Protocols Requesting CRC Support)
Clinical Research Center (CRC)
University of Connecticut Health Center
263 Farmington Avenue, Farmington, CT 06030-3805
TEL: (860) 679-4145 FAX: (860) 679-1454

SECTION 1 – GENERAL STUDY INFORMATION

1.0 Date:

1.1 Name of Principal Investigator:

1.2 Complete Project Title:

1.3 Is this study: investigator-initiated research industry-initiated research Other (specify):

1.4 Is this a Federally-funded, Multi-Center Clinical Trial: Yes No

1.5 Please indicate if this study is one of the following categories: Pediatrics HIV/AIDS Clinical Trial N/A

SECTION 2- FUNDING INFORMATION & APPLICATION INSTRUCTIONS

2.0 Please indicate all funding sources for this project. If this particular study is part of a Center Grant/Program Project Grant/Co-operative Agreement (or if you are the Program Director for any of those), please list only those costs associated with this particular project, not the entire grant. Include with your application to the CRC the proposal and budget pages submitted to the Funding Agency. If you have received funding, include the budget detail for the amount that was approved.

	Funding Source 1	Funding Source 2	Funding Source 3
Funding Status:	<input type="checkbox"/> Funded <input type="checkbox"/> Under Review	<input type="checkbox"/> Funded <input type="checkbox"/> Under Review	<input type="checkbox"/> Funded <input type="checkbox"/> Under Review
Full Name of Funding Agency/Source (e.g., NIDDK, Pharmaceutical, Internal Funds, Departmental Funds):			
Total Funds available/expected:			

2.1 There are two methods to apply to CRC, based on Funding Source availability provided in item 2.0. **Please select a checkbox for one of the two options below and follow the application instructions:**

Option #1: Partial funding available. For partially-funded projects, the CRC Scientific Advisory Committee (SAC) will review the project and resource request. **Generally, investigators are expected to pay for 80% of CRC resources (including CRC staffing time and effort) that are approved by SAC.** SAC meets the 3rd Thursday of every month and application documents should be received in CRC by the last day of the preceding month. **Submit the following documents electronically to Ms. Lisa Godin (godin@nso.uchc.edu) and send one hardcopy signed to Ms. Godin (CRC, MC-3805).**

- Electronic version of the Research Protocol, IRB Application (including Appendices A, B, C if applicable, and D), Informed Consent Form(s), and HIPAA Authorization. The research protocol must include: specific aims, background and significance, methods, and references. If the proposed study has already been approved for funding by NIH, a Foundation, HCRAC, or as an investigator-initiated industry-funded study, the final proposal used to obtain funding can be submitted.
- Principal Investigator CV (NIH biosketch format is preferred)
- **Electronic version of the IRB Approval letter and documents
- **Reviews/critiques from the funding agency (e.g., Summary Statement, if NIH) and your response; Award Letter; results of any other scientific reviews
- **Approved budget from funding agency and budget justification for the entire funding period

***If these documents are not available at the time of the application, please indicate that in a cover memo and forward the materials once they become available.*

Option #2: Full funding available (i.e., request CRC resources as a “purchased service”). For investigators who can pay 100% of the cost of the requested service, CRC may provide resources on a fee-for-service basis. The CRC Governance Committee will review the resource request and meets the 2nd Tuesday of every month. **To apply under Option #2, submit the following documents electronically to Ms. Marsha Murray (mmurray@uchc.edu):**

- Appendix A (this form) and Appendix B (if protocol doesn't include a DSMP/B)
- Clinical Trial Feasibility Checklist ([click here](#))

- Electronic version of the research protocol
- Visit schema / table of study visits (if not included as part of protocol)
- Budget workbook summary (from the Office of Clinical and Translational Research; or, if Dental study, from the Department of Oral Health and Diagnostic Sciences)
- Grantee award letter
- Sponsor's proposed budget
- **Reviews/critiques from the funding agency (e.g., Summary Statement, if NIH) and your response
- **Informed Consent Form(s) and HIPAA Authorization
- **Final contract

***If these documents are not available at the time of the application, please indicate that in a cover memo and forward the materials once they become available.*

Please note that all studies utilizing CRC resources require a scientific review.

SECTION 3 – CRC RESOURCES

3.0 Please provide justification for requesting CRC resources. Enter your explanation here:

3.1 In the tables below, place an X after the CRC Core resources being requested. This information is needed by the Scientific Advisory Committee or Governance Committee to evaluate your request and by CRC staff to implement the request, once approved. If you need to speak to more than one person in the CRC regarding your study needs, it may be helpful to schedule a meeting. Please contact Lisa Godin (x 4145) to arrange the meeting, or contact Pam Fall (x3681) if you have any questions.

NOTE: The CRC typically does **NOT** cover costs related to: investigator travel to scientific meetings, investigator salary support, subject payments/stipends (in some cases, non-NIH funds may be available), costs associated with routine clinical care, data entry/data management, or administrative/financial management.

Please specify which resources you are requesting from the CRC and which resources the PI will provide/pay for by checking the appropriate boxes below. Be as specific as possible to avoid delays in processing your application.

Clinical Core / Study Coordination (Contact Tom Kiely, 679-1707) Kiely@nso.uchc.edu			Pharmacy (Contact Ruth LaCasse, 679-2085) rlacasse@uchc.edu		
	<i>CRC</i>	<i>PI</i>		<i>CRC</i>	<i>PI</i>
Screening / Recruitment			Drug Accountability		
Informed Consent Process			Randomization		
Study Visits			Drug/Placebo Preparation		
Phlebotomy/Specimen Collection			Other (Please Specify):		
Study Medication Admin. (e.g., PO, IV, etc.)					
Study Coordination			DEXA Scan / Body Composition Studies (Contact Linda Gregory, 679-2673) lgregory@uchc.edu		
Registered Nurse - enter hours/week in box:					
Research Assistant - enter hours/week in box:					
Medical Exam Room Use					
IRB submission(s)					
SAE/AE tracking and reporting				<i>CRC</i>	<i>PI</i>
Dental Assistant - enter hours/week in box:			Specify body area (e.g., total body, wrist, hip, spine, other) here:		
Dental Operatory Use			Raw data from DEXA		
Research record chart assembly and maintenance			Analysis of DEXA		
Other (Please Specify):					

If requesting ancillaries, please specify ancillary and number per subject.

JDH/UMG/UD Ancillary Services <i>(diagnostic or clinical tests or procedures)</i>	Total Number of Tests/Procedures <i>Specify # per subject</i>	Funding/Payment Source	
		<i>CRC</i>	<i>PI</i>

Core Lab (Contact Pam Fall, 679-3681) fall@nso.uchc.edu		
	<i>CRC</i>	<i>PI</i>
Processing		
Shipping		
Specimen Storage		
Core Lab Tests/Assays (Specify below)		

If Core Lab tests/assays are requested, please indicate what and number of tests/assays below:

CRC Core Lab Tests / Assays	Total Number of Tests / Assays	Labor		Kits/Supplies	
		<i>CRC</i>	<i>PI</i>	<i>CRC</i>	<i>PI</i>

Informatics (Contact Ken Dugas, 679-2683) dugas@uchc.edu			Administration and Financial Management (Contact Pam Fall, 679-3681) fall@nso.uchc.edu		
	<i>CRC</i>	<i>PI</i>		<i>CRC</i>	<i>PI</i>
Case Report Form (CRF) Design			Pricing of Services (i.e., ancillary costs)		
Double Data Entry			Contract/Purchase Service Agreement (PSA) Preparation and Routing		
Application Development			Ancillary Services Bills Processing		
Database Development			Subject Payment Processing		
Interactive Voice Response (IVR)			Recruitment Ads Placement		
Consultation			Meal Passes Processing		
Other (Please Specify)			Other (Please Specify)		

Biostatistics (Contact Rich Feinn, 679-1596) rfeinn@uchc.edu		
	<i>CRC</i>	<i>PI</i>
Study Design and Analytical Methods		
Power Analysis		
Data Analysis		
Consultation/Other		