

**University of Kentucky
Clinical Research Development and Operations Center**

Please complete the following CR-DOC Protocol Application. Our Mission is to provide optimal support to Principal Investigators and Study Coordinators to facilitate the implementation of clinical research. If you need assistance, contact the following:

Please include the following with your application submission:

<ul style="list-style-type: none"> • CR-DOC application
<ul style="list-style-type: none"> • Copy of research protocol including the following information: Clearly stated hypothesis <ul style="list-style-type: none"> • Abstract • Specific Aims • Background/significance • Preliminary Studies • Experimental Design/Methods (include a flow sheet or schema) • Statistical Design <u>please correspond with Dr. Kryscio.</u> • Current Biographical sketch of each PI and Co-I (2 page PHS 398) • Current Other Support of each PI and Co-I (PHS 398 Format) • Literature cited
<ul style="list-style-type: none"> • Copy of the UK IRB application, including consent form. Upon IRB approval, submit a hard copy of the approval letter and the stamped and dated approved consent. <u>Projects cannot commence without IRB approval.</u>
<ul style="list-style-type: none"> • Copy of study flow sheet (chronological list of study procedures)

Prior to study implementation you must meet with the GCRC nursing staff to review the final implementation details of your project and if necessary schedule an in-service for the GCRC patient care staff.

PUBLICATION CREDIT: Continued funding for the CR-DOC requires citation of support in all publication of research that results from utilization of CR-DOC resources. Thus, *it is critical to the future of the CR-DOC* that investigators acknowledge support in all pertinent publications with the statement: **This investigation was supported by the University of Kentucky Clinical Research Development and Operations Center.** The reprint citing the CR-DOC support should be sent to GCRC administrative offices.

Clinical Research Development and Operations Center Protocol Application

Project Title:

(Title **must** match IRB consent form and originally funded grant—if applicable)

Funding Source and Grant Number:

IND #:

Principal Investigator:

Phone:

Department:

Bldg/Room:

Beeper:

Email:

Co-Investigators (names, titles)	Department	Phone/Beeper

Names of individuals IRB-approved to obtain consent (attach IRB letter and/or key personnel list)

Research Coordinator:

Phone/Beeper:

Email:

Contact person for billing / financial questions:

Phone/Beeper:

Estimated duration of patient enrollment and project:

SUBJECTS: Age range:

Diagnosis:

Demographics: Gender and Minority Inclusion - Study Population Projections

The National Institutes of Health requires that all proposals for utilization of the GCRC must include a description of the anticipated racial/ethnic and male/female compositions of your disease-specific study population. If women and minorities, or children will not be included in your study populations, a specific justification for this exclusion must be provided. Also, if numbers in table two are substantially lower than table one, a plan should be described that will appropriately increase the participation of relevant groups. 323-6481, The Director of Operations can help the investigator with this section, if needed.

Total Enrollment Report: Number of Subjects				
Ethnic Category	Sex/Gender			
	Females	Male	Unknown or Not Reported	Total
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of Subjects*				*
Racial Category				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
Racial Categories: Total of All Subjects*				*

* These totals must agree

** These totals must agree

CR-DOC Protocol Application: Resource Request

Administrative (Abby Cosentino-Boehm 3-7939; alcose0@uky.edu)

Patient Category: Indicate type of research subject (A, B, D, or combination)

“A” - Patients/Subjects admitted solely for research purposes; all hospital costs are provided by the investigator’s grant and/or CR-DOC.

“B” - Patients admitted for routine medical care and who simultaneously participate in a research project; non-research hospital costs are covered by the third party carrier.

“D” - Patients/Subjects who participate in industry-initiated studies; all hospital costs are provided by the drug company.

CR-DOC Time and Space requested.				
<i>Include anticipated requirements for subjects recruited who do not complete the study as well as subjects who will complete the study.</i>				
Type of Visit	Total Number of Participants	Number of Visits/Admissions per Subject	Total Number of Visits/Admissions	Average Time per Visit
Outpatient				
Inpatient *				

***Minimum request of one overnight stay past 12 midnight.**

Please note that any changes to protocol effecting budgetary support must be approved by the Scientific Advisory Committee prior to implementation.

Please briefly answer the following questions:

- 1) What special services do you request from the CR-DOC, i.e. Nursing, Dietary, EP, Informatics, Core Lab?
- 2) Could you perform your research without the CR-DOC and where?
- 3) Future direction and funding opportunities?

PATIENT CARE CORE:**(Linda Rice, RN, BSN, lsrice0@uky.edu, 3-6481; fax 7-9560):***Please summarize your request for duties to be performed by the CR-DOC nursing personnel:*

Procedure	Outpatient	Inpatient	Comments
Standard orders: Development of computerized physician orders printing & review with PI/MD. Nursing standard is inpatient and outpatient.			
Complete vital signs: Nursing standard is Q Shift inpatient and Q Visit outpatient. If needed more often please state parameters needed and frequency I.E. HR & BP Q 5 min X 1hr etc.			
Venipuncture: Includes IV access for labs.			
Specimen collection: GCRC staff collects all specimen samples (blood, saliva, urine, etc) on the GCRC. Processing: GCRC staff is responsible for processing & distribution (send to hospital lab, shipping, freeze and hold, etc) of all specimens obtained in the GCRC. The GCRC does not generate lab reports.			
Blood			
Urine			
Other lab specimens			
Special needs: Would you like nursing to attend to any needs of the patients in this study?			
Assessments: Nursing standard is initial nursing H&P and routine. Inpatient has routine assessments Q shift. Outpatient has routine (brief H&P) assessment with each visit. Others include wound assessments, MMSE, GCS, completion of study questionnaires etc.			
Procedures: EKG, PFT, cardiac monitoring etc.			
Equipment: need it, we may have it. I.E. EKG machine, metabolic cart, etc.			
Supplies			
Patient education: <u>Any education</u> required for patients in this study. Nursing standard is research process on admission and procedures I.E. venipunctures, IV's, PFT, EKG etc.			
Medications: Study medications you would like GCRC nurses to administer both inpatient and outpatient. If patient is taking own supply please indicate. **			

*****If your protocol requires the dispensing of an investigational drug, contact Steve Sitzlar, Investigational Drug Pharmacist (IDS) (Phone: 3-2894)***

Nutrition
(Jennifer Fuller, RD, 3-3805, jennifer.fuller@uky.edu):

Procedure	Outpatient	Inpatient	Comments
Anthropometrics – Height, weight, body mass index, arm muscle circumference			
Bioelectrical Impedance			
Calorie Counts			
Diets:			
Ad lib			
Calculated			
Specially timed			
Standardized			
Therapeutic*			
Diet history- 24 hour recall, 3 day diet diaries with analysis, food frequency questionnaires			
Patient Education I.E. how diet relates to the study, record keeping techniques, therapeutic diet instruction upon discharge			
Single meals or snacks: breakfast, lunch or light snack during or after completion of fasting blood draws or study session			

*Indicate nutrient goals of research meal, therapeutic diet, or research diet:

Ancillary Services**EKG, Radiographs, Nuclear Medicine, etc, Laboratory:**

List all **clinical** laboratory tests and other ancillary services for which your requesting GCRC support (EKG, Radiology, Nuclear Medicine, etc) pertinent to your study for each Outpatient and/or Inpatient Admission for a single year.

Please do not include Core Lab tests on this page.

R	S	CHEMISTRY PANELS*	R	S	R	S	R	S	SEROLOGY
	P1	Electrolyte Panel				Hemogram		CRP	C-Reactive protein
	P2	Basic Metabolic Panel				Hemogram w/diff		HIV	HIV antibody
	RHF	Research Hepatic Fxn				Manual WBC diff		RPR	RPR
	P4	Comprehensivne Panel				Platelet count		HEP	Hepatitis Diagnostic panel
	LIPID	Lipid panel				Hemoglobin	R	S	MICROBIOLOGY
	TY1	Thyroid panel1		HCT		Hematocrit		ARBLC	blood culture-aerobic
	TY2	Thyroid panel2		WBC		WBC Count		ANBLC	blood culture-anerobic
	RC9	Research Chem 9		EOCT		Esosinophil count		BLC	blood Cult. Aer&Anaer.
	RC19	Research Chem 19		ESRW		Sed rate (Westgr)		WDC	Wound Culture
	RC23	Research Chem 23		RETC		Reticulocyte count			Gram Stain
	ALT	ALT			S	HEMOSTASIS	R	OTHER TESTS	Do not list Core Lab tests here
	CA	Calcium		PT		Prottime/INR			
	CHOL	Cholesterol		PTT		PTT			
	HCL	HDL chol with total		CFGN		Fibrinogen			
	CO2	CO2, total		TCT		Thrombin time			
	CREA	Creatinine		XDP		X-linked FDP			
	FER	Ferritin		BT		Bleeding time			
	GGT	Gamma GT							
	GLU	Glucose							
	HCG	HCG, total beta			S	URINE TESTS	R		
	LDH	LDH, total		UAR		UA w/reflex micro			
	MG	Magnesium		PREG		Pregnancy, Qual.			
	PHOS	Phosphorus		UAM		UA w/mand. Micro			
	TP	Protein, total		UREO		Urine eos. Ct.			
	URIC	Uric acid		URI		Urine screen			
	CK	CK TOTAL		URNC		Urine culture			
	CKIS	CK MB, w/Total		ABUS		Drugs of abuse			
	ALCO	Alcohols							
	AM	Amylase		24 hr. urine					
	LPSE	Lipase		START TIME:					
	ICA	Ionize calcium		STOP TIME:					
	HBSA G	Hepatitis B surface AG							
	LA	Lactic acid							
				ANALYTES NEEDED:					

J980 (9/98)

R-ROUTINE S-STAT

PT1- LAB

PT2-RESEARCH AREA

Specify any special supply needs or transportation requirements for sample collections:

Exercise Physiology Laboratory:
Jody Clasey, PhD. 7-8055, jody.clasey@uky.edu

Available Procedures		Comments
Graded Exercise Test (please specify ergometry type)		
Oxygen Consumption		
Lactate Concentrations		
Acute Exercise Bout (please specify ergometry type)		
Oxygen Consumption		
Lactate Concentrations		
Basal Metabolic Rate (BMR)		
Resting Metabolic Rate (RMR)		
Bedside Calorimetry (Repeating)		
Dual Energy Absorptiometry (DXA)		
Total Body		
Lumbar Spine (AP)		
Lumbar Spine (Lateral)		
Proximal Femur (Rt)		
Proximal Femur (Lt)		
Forearm (Rt)		
Forearm (Lt)		
Single Frequency Bioelectric Impedance (BIA)		
Multi-Frequency Bioelectric Impedance (BIA)		
Air Displacement Plethysmography		
Thoracic Volume		
Hydrostatic Weighing		
Residual Lung Volume		
Anthropometry (please list sites requested)		
Skinfold		
Circumference		
Structural		
Total Body Water (D ₂ O)		
Respiratory Water		
Plasma		
Extra-Cellular Water (NaBr)		

DATA SAFETY AND ANALYSIS CORE:

Informatics: The CR-DOC provides support for clinical research data management to investigators/clinical coordinators. If you plan to use our services, please indicate in the table below.

Resource		Comments/details
Database Consulting		
Computing Resources Consulting		
Data Storage Consulting		
Forms Data Collection Techniques Consulting		
Web-based Data Collection		
Data Safety Assurance and Compliance		

Biostatistics: (Richard Kryscio, Ph.D., 7-4064; Kryscio@uky.edu). Dr. Kryscio reviews every protocol for Biostatistical feasibility and is available for consultation by appointment.

Resource		Comment
Consultation		
Study design		
Sample size determination		
Statistical Analysis		
Statistical Software (Sigma STAT or NIH Prophet)		

DATA AND SAFETY MONITORING PLAN (All questions must be answered)

Qualifications of the Research Team and Environment

The following individuals are involved in the design and conduct of the study:

Name	Title	Role in study	“Protecting human subjects” training*	HIPAA training** (Yes only)	Obtain consent (Yes/No)	Hospital Admitting Privileges (Yes/No)
(May add or delete rows)						

*Indicate that there is documentation with the UK-Clinical Research Organization for having taken the Dunn and Chadwick (D&C) test, CITI course, or Shulman Associates (SA) course.

**All investigators and key personnel must indicate that they have received training in the Health Insurance Portability and Accountability Act (HIPAA) and may be asked to provide documentation.

If the protocol imparts more than minimal risks due to disease(s) and/or procedure(s), indicate which investigators have expertise and for how many years (or indicate “not applicable”):

If the protocol involves packing/shipping of biologic or biohazardous material, indicate the name(s) of those individuals with Department of Transportation/International Air Transportation Association (DOT/IATA) certification, (or indicate “not applicable”):

Indicate (Yes/No) if there is any financial conflict of interest for any investigator, key personnel, their spouse, or their children according to the University of Kentucky ARII-4.0-4.

If Yes, explain and indicate what measures were taken to minimize or eliminate conflict:

Safety Monitoring

Please list the ANTICIPATED adverse events and the range of their expected severity grades (using the NCI’s Common Toxicity Criteria, version 2.0 listed below the table). This list should correspond with risks described in the IRB-approved consent form.

Anticipated Adverse Events	Severity Grade

(May add or delete rows)	

NCI Severity grades:

1 = Mild adverse event, 2 = Moderate adverse event, 3 = Severe and undesirable adverse event, 4 = Life-threatening or disabling adverse event, 5 = Death related to adverse event.

Besides the **UK IRB**, to what **other agencies** will **serious adverse events** (SAEs) be reported [e.g. NIH (specify institute), FDA, sponsor (specify), the Office of Biotechnology Activities (OBA, for gene transfer), the Data and Safety monitoring board of the study, if any), or Institutional Biosafety Committee (IBC)], or indicate "none":

Indicate that the principal investigator (PI) and key personnel have read and understand the UK Policy on Prompt Reporting for Unanticipated Problems, Serious or Life-threatening Events, and Related Anticipated and Unanticipated Deaths.

[**Web access:** [http://www.research.uky.edu/ori/SOPs Policies/AE_policy_6-5-06.pdf](http://www.research.uky.edu/ori/SOPs_Policies/AE_policy_6-5-06.pdf)]

PI and Key Personnel have read and understand policy: (place "X" in box if true)

Or **Not Applicable:**

Confidentiality

At what **location** will informed consent be obtained? _____

Indicate how the protocol will be **HIPAA compliant**: (place "X" in appropriate box)

Subjects will sign an approved HIPAA Authorization Form.

A Waiver of HIPAA Authorization has been requested and approved.

A HIPAA De-identification Certification signed by PI covers the protocol.

This research protocol is not regulated by HIPAA

Data Monitoring

Indicate in what **format** and **where** all data from this protocol will be **stored**:

Indicate whether accrued data will be monitored **continuously or at pre-defined intervals** and by **whom** will the data be monitored? (If at intervals, indicate when data will be reviewed).

Briefly describe plans for insuring **data accuracy** and **protocol compliance**. Include any quality control measures, who is responsible for implementing, and what procedures are in place to ensure protocol adherence:

Indicate (Yes/No) whether the protocol has a designated **Data Safety Monitoring Board*****:

If Yes, indicate whether it is **external** to UK or an **internal** UK board: _____

If an external board exists, it must be adequately described in the Research Description.

If an internal UK board has been formulated, list its membership (including each member's expertise/specialty), list the DSMB's Charter and the DSMB's Responsibilities:

***A DSMB is only needed for **interventional** trials in the following circumstances (from Ellenberg SS, Fleming TR, DeMets DL. Data Monitoring Committees in Clinical Trials. J. Wiley 2002, pg 13.)

1. If the trial is intended to provide definitive information about effectiveness and/or safety of a medical intervention.
2. If there are prior data to suggest that the intervention being studied has the potential to induce potentially unacceptable toxicity.
3. If the trial is evaluating mortality or another major endpoint, such that inferiority of one treatment arm has safety as well as effectiveness implications.
4. If it would ethically important for the trial to stop early if the primary question addressed has been definitively answered, even if secondary questions or complete safety information were not yet fully addressed.