Clinical Research Center (CRC) Protocol Submission Application

Request for CRC Services

**ALL ITEMS MUST BE COMPLETED**

* **Documentation of ERC approval must be submitted with this application. Review for use of the CRC will not take place without documentation of ERC approval.**

1. General Information

* 1. **Study Title:**

**1.2** **Principal Investigator:**

 Name:

 Title:

 Department:

 Phone:

 E-Mail:

**1.3** **Co-Principal Investigator(s):** (Individuals who share full responsibility for the study with the PI):

 Name:       Department:

 Name:       Department:

**1.4** **Sub-Investigator(s):** (Individuals who assist PI or Co-PI in certain assigned aspects of the study):

 Name:       Department:

 Name:       Department:

 Name:       Department:

 Name:       Department:

**1.5** **Study Coordinator:**

 Name:

 Title:

 Degree:

 Department:

 Phone:

 E-Mail:

1. **Source of Funding/Sponsorship**

**2.1** Check all appropriate boxes for funding/sponsorship for this research.

 [ ]  No Funding or Sponsor

 [ ]  Department Funding

 Department Name:

 [ ]  Industry Sponsored / Investigator-Initiated

 Sponsor Name:

 [ ]  Industry Sponsored / Industry-Initiated

 Sponsor Name:

 [ ]  Government Agency

 Agency Name:

 Grant Number:

 [ ]  Foundation

 Foundation Name:

 Grant Number:

**3. Rare Disease/Condition**

**3.1** Does this study evaluate a disease that would qualify as a Rare Disease or Condition as defined by the NIH?

 [ ]  Yes [ ]  No

**4. Inclusion of Children**

**4.1** Are children (**under the age of 21**) are to be included?: [ ]  Yes [ ]  No

**5. Drugs, Devices, and Vaccines**

**5.1** Will drugs, biologics, or devices be used in the study? [ ]  Yes [ ]  No

 **If YES**, please indicate name of drug or biologic:

**5.2** Is the drug/biologic/device FDA approved or exempt? [ ]  Yes [ ]  No

 **If NO**, please provide the following:

 IND No.:

 Who holds the IND?

 Is there is a “Safe to Proceed” letter: [ ]  Yes [ ]  No

**6. CRC Need:**

**6.1** Please justify **WHY** CRC resources are needed:

7. Participant Projections

**7.1** Projected start date:

**7.2** Expected duration of study from initial enrollment to completion of last subject:      year(s)

**7.3** Please project the number of ***NEW*** subjects for each year (March 1st to February 28th) and then provide the total number for the duration of the study.

 Inpatient Outpatient

1st year

2nd year

3rd year

4th year

5th year

Total:

**7.4** Are subjects to be studied as inpatients (i.e. the subject will be in a CRC bed at midnight)?

 [ ]  Yes [ ]  No

 **Per Subject**: number of days per admission on the CRC:

 Number of admissions on the CRC:

 Total days required on the CRC:

**7.5** Are outpatient visits included in study?

 [ ]  Yes [ ]  No

 **If YES**:

 Will these outpatients be seen on the CRC? [ ]  Yes [ ]  No

 **If NO,** where will they be seen?

 **Per Subject**: number of visits on the CRC:

 Approximate length of visit on the CRC:       hours

 Total hours per subject on the CRC:

8. CRC SERVICES

Please indicate if the following services are needed:

**8.1 Nursing Services:**

[ ]  Yes [ ]  No

**If YES,** check all that are needed:

[ ]  Routine patient care (i.e. ht, wt, vital signs)

[ ]  Special cardiac monitoring (Telemetry)

[ ]  ECG

[ ]  Biopsies Type of Biopsy:

[ ]  Non-serial blood collections

[ ]  Serial blood collections

[ ]  Saline-locks

## [ ]  IV lines

## [ ]  Subcutaneous injections/teaching

## [ ]  IV infusions

[ ]  24 hour urine collections

[ ]  Stool collections

[ ]  Other:

**8.2 Pharmacy Services**:

[ ]  Yes [ ]  No

 **If YES**, Indicate the service:

 **[ ]** Drug Accountability **[ ]** Randomization **[ ]** Drug/Placebo Preparation **[ ]** Other

**8.3 BIOSTATISTICS**

[ ]  Yes [ ]  No

 **If YES**, Indicate the service:

 [ ] Study Design & Analytical Methods [ ] Data Analysis [ ] Consultation/Other

**8.4 Other Services**:

[ ]  Yes [ ]  No

 **If YES**, Indicate the service, the # of subjects or patients and the # of tests per subject:

      # of subjects       # of tests /subject

**8.5 Bionutrition:**

## Are regular meals or snacks needed? (check yes for meals post fasting, visits >4 hours, and overnight) [ ]  Yes [ ]  No

**8.5.1 Bionutrition Services (other than regular meals or snacks)**

 [ ]  Yes [ ]  No

**If YES,** check all that are needed:

[ ]  Standardized meals (check yes if any food/nutritional manipulation is necessary)

[ ]  Metabolic or constant diet (weighed)

[ ]  Computerized dietary analysis (e.g., food records, 24 hr recall, food frequency)

[ ]  Pre-admission counseling for dietary control (e.g., high carbohydrate diet prior to OGTT)

[ ]  Patient nutrition counseling/education

[ ]  Other (e.g., find appropriate nutrition assessment tools):

**8.6 Laboratory Services:**

[ ]  Yes [ ]  No

**If YES,** check the services needed:

[ ]  Processing only

 # of potential samples      length of storage duration

[ ]  Freezer space

 # of potential samples      length of storage duration

**8.6.1** Is special handling of samples required?

[ ]  Yes [ ]  No

**If YES**, please explain:

Other: