Protocol Submission Application

Request for Coordinator Services

**ALL ITEMS MUST BE COMPLETED**

* **The study protocol and informed consents must be submitted with this application.**

1. General Information

* 1. **Study Title:**

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

 Name:

 Title:

 Department:

 Box #:

 Phone:

 E-Mail:

**1.3** **Study Coordinator:**

 Name:

 Title:

 Department:

 Box #.:

 Phone:

 E-Mail:

**1.4 Supervising Coordinator (person who will be supervising the trainee):**

 Name:

 Title:

 Department:

 Box #.:

 Phone:

 E-Mail:

**1.5** Address where coordinators will be working:

1. **Source of Funding/Sponsorship**

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

 [ ]  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:

 [ ]  Other

 Funding Source:

**2.2 Please provide a FAO number:**

**3. Inclusion of Children**

**3.1** Are children (**under the age of 18**) are to be included?: [ ]  Yes [ ]  No

**4. Drugs, Devices, and Vaccines**

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

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

**5. Coordinator Need:**

**5.1** Please justify **WHY** coordinator resources are needed:

**5.2** List the activities/tasks the coordinators will be engaged in:

**5.3** Number of participant to be enrolled in trial:

**5.4** How many hours per week that the coordinator or coordinator trainee is to be hired (1.0 FTE, 0.5 FTE, etc.)

**5.5** What length of time will the coordinator/coordinator trainee be working on the trial:

6. Participant Projections

**6.1** Projected start date:

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

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

 [ ]  Yes [ ]  No

 **If YES:**

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

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

**6.4** 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?