Protocol Submission Application

Request for Coordinator Services

Introduction

The CTSI Coordinator Services program was developed to 1) provide investigators with temporary (<1 year) coordinator support until permanent staff could be hired and 2) provide support to investigators who need ≤50% support for a particular study. The service is not for providing long-term coordinator support that could be more effectively managed with existing department staff or new department hires. The coordinator pool currently consists of Human Subject Research Coordinator Trainees who after successfully fulfilling competencies will be promoted to Human Subject Research Coordinator (HSRC) I positions. As the pool grows we will have trainees and HSRC I staff available.

Applications are accepted on a rolling basis throughout the year and studies will be selected for support if there are staff available during the time period requested. The investigator, a HSRC II or Sr. HSRC must be available to the CTSI staff member to handle questions. If a trainee is hired, a Sr. HSRC must be available to supervise until the trainee is promoted to a HSRC I. The services program will select the staff most qualified to complete the work requested.

In the event we have more applications than can be filled, studies will be ranked and chosen using the following criteria in this order:

* Studies that are federally-funded will be given priority over industry-sponsored
* Studies utilizing the Clinical Research Center will be given priority
* Studies that are interventional, prospective investigations of a device, drug or biologic will be given priority over observational, registry or retrospective studies
* Studies being conducted in departments that volunteered to host the CTSI trainees for shadowing will be given priority
* The investigator must be in good standing with the Office of Human Subject Protection

Before service begins a 1 hour Zoom meeting must be completed with the study investigator, a department coordinator, CTSI coordinator service manager and CTSI hired trainee/HSRC I. The purpose of this meeting is to review the protocol, the investigator’s needs and answer questions. At this meeting the CTSI will review what the service can provide based on coordinator competencies established by the Association of Clinical Research Professionals (ACRP).

The coordinator services manager will request feedback on performance at 1 month, 3 months and 6 months of service. We will make every effort to work with you if issues arise, however, coordinator services can be terminated at any time if adequate supervision or department support are not provided or issues arise that cannot be resolved.

If you would like more information about the qualifications of our coordinators and the ACRP competencies, please email JoAnne\_VanBuskirk@urmc.rochester.edu.

**ALL ITEMS MUST BE COMPLETED**

* **The current version of 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 coordinator on site if different from study coordinator):**

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 participants to be enrolled in trial:

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

**5.5** What duration of time will the coordinator/coordinator trainee be working on the trial in weeks or months:

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?