Puerto Rico Clinical and Translational Research Consortium

Study Initiation Meeting

I. Procedure Title: Study Initiation Meeting

II. Overview/Procedure Description:

1. The Clinical Research Resources and Facilities Core (CRF) Coordinator is responsible for conducting the study initiation meeting for each protocol approved at the Puerto Rico Clinical and Translational Research Consortium (PRCTRC)

2. **If requesting include only services from the Technologies and Resources for Core Laboratories (TRCL):** The TRCL Laboratory Manager is responsible for conducting the study initiation meeting for each protocol approved at the PRCTRC.

III. Purposes:

1. For the Investigator
    a. To understand the specific activities required in order to begin receiving services from the PRCTRC,

    b. To meet the PRCTRC personnel who will provide support for the study.

2. For the PRCTRC Staff
    a. To meet the Principal Investigator (PI) and the staff who will be conducting the study;
    b. To understand the study's objectives and activities.

IV. Area(s) of Responsibility:

Clinical Research Resources and Facilities Core (CRF), Technologies and Resources for Core Laboratories (TRCL), Administrative Core (AC), Principal Investigator (PI), Co-Investigators (CO-PIs), Study Coordinator (SC), Regulatory Knowledge and Support Core (RKS)

V. Procedure Details:

Responsibilities Before the Study Initiation Meeting:

1. Study Principal Investigator:

a. After receiving the PRCTRC Approval Letter, the Principal Investigator (PI) is responsible for contacting the CRF Coordinator in order to make arrangements for the study initiation meeting;
b. After receiving the confirmation email from the CRF Coordinator for the study initiation meeting, the PI is responsible of making arrangements for her/his staff to attend the initiation meeting;

c. If pertinent, the PI will prepare documentation related with the study (hard copy and/or Power Point Presentation) to present his/her needs to the PRCTRC staff during the initiation meeting.

2. Clinical Research Resources and Facilities Core Coordinator:

a. Once the Principal Investigator has agreed on a date, the CRF Core Coordinator is responsible for sending an email to the PI with the date, time, and location of the meeting, including the *agenda* (see **Attachment A**);
b. The CRF Core Coordinator is responsible for sending an Invitational email for the meeting to the PRCTRC key personnel, including the *agenda* (see **Attachment A**).

3. Clinical Research Resources and Facilities (CRF) Core:

a. The Head Nurse is responsible for meeting with the nursing staff and reviewing the Application Form in order to:

- Discuss and evaluate the Nursing Services requested by the PI. Complete an assessment of the nursing services requested by the PI;
- Clarify any doubt or question related to the protocol nursing procedures (ex. Vital signs, phlebotomy, anthropometric measures, etc.)

4. Technologies and Resources for Core Laboratories (TRCL):

a. The Laboratory Manager is responsible for meeting with the Laboratory staff and reviewing Application Form in order to:
    - Complete an assessment of the laboratory services requested by the PI;
    - Complete an assessment of the availability of the equipment requested by the PI (if applicable);
    - Dedicate attention to areas of discussion or questions;
    - Review the study's Laboratory Manual.

5. Administrative Core (AC):

a. The PRCTRC Administrator is responsible for meeting with the Administrative staff and reviewing the Application Form in order to:
    - Complete an assessment of the services requested by the PI;
    - Prepare an Administrative fee draft for the study.

6. Regulatory Knowledge and Support Core (RKS):

a. The Research Subject Advocate is responsible for:
    - Create a study file with regulatory documents (IRB, IBC, IACUC);
    - Review the *Delegation of Responsibilities and Signature Log* to ensure study personnel's responsibilities are well defined;
    - Review that all personnel listed in the *Delegation of Responsibilities and Signature Log* submit updated training certifications and other requirements.

Responsibilities During the Study Initiation Meeting:

1. Study Principal Investigator:

a. The PI will:
    - Present a summary of the protocol including: background and purpose of the study, the number of participants to be recruited, the inclusion and exclusion criteria, recruitment period, study treatment procedures, special tests and

procedures, study drug management (if applicable) and specimen management (if applicable);
- Confirm that all materials and/or equipment necessary to conduct protocol related activities have been received at the PRCTRC. These may include, but are not limited to: Procedure Manual (if any), Test Articles (if appropriate to study), laboratory kits, laboratory manual and supplies (if appropriate to study), and any other materials and/or equipment as appropriate to study.
- Answer questions that result from the protocol presentation;

2. Clinical Research Resources and Facilities Core Coordinator:

a. The CRF Core Coordinator will:
- Conduct the meeting;
- Have all participants sign an attendance list;
- Take notes of the agreements;
- Close the meeting.

3. Clinical Research Resources and Facilities (CRF) Core:

a. The Head Nurse will:
- Review the *Nursing Services Sheet*;
- Clarify any doubt or question related to the Nursing Services required;
- Record items that are relevant to nursing services and facilities;
- Go over the CRF SOPs.

3. Technologies and Resources for Core Laboratories (TRCL):

a. The Laboratory Manager will:
- Clarify any doubt regarding lab procedures and the use of equipment requested (if applicable);
- Dedicate attention to areas of discussion or questions;
- Record items that are relevant to lab procedures and facilities;
- Go over the TRCL SOPs.

5. Administrative Core (AC):

a. The PRCTRC Administrator will:
- Present the Administrative fee draft;
- Answer any question about the Administrative fee draft;
- Request contact information for the invoice procedure;
- Go over the AC SOPs.

6. Regulatory Knowledge and Support Core (RKS):

a. The Research Subject Advocate will:
- Request documentation, if needed, for compliance with regulatory requirements
- Match the study staff with the *Delegation of Responsibilities and Signature Log* ;
- Go over the RKS SOPs.

Responsibilities After the Study Initiation Meeting:

1. **Study Principal Investigator:**
   a. The PI will:
      - Keep ongoing communication with PRCTRC personnel;
      - Inform any changes to protocol requirements.

2. **Clinical Research Resources and Facilities Core Coordinator:**
   a. The CRF Coordinator will:
      - Prepare a meeting report and send it to the PI and other cores;
      - Follow up on areas identified for further clarification;
      - File the original attendance list in the study record;
      - Provide a copy of the attendance list for the RKS Core file.

3. **Clinical Research Resources and Facilities (CRF) Core:**
   a. The Head Nurse will:
      - Follow up any issues identified for further clarification;
      - Maintain frequent communication with the PI;
      - Frequently review the protocol procedures and implement any change approved by the IRB.

4. **Technologies and Resources for Core Laboratories (TRCL):**
   a. The Laboratory Manager will:
      - Follow up on areas identified for further clarification;
      - Keep ongoing communication with the PI;
      - Take care of any question, situation or change related with TRCL, which may arise during the period that the protocol is active.

5. **Administrative Core (AC):**
   a. The Administrator will:
      - Follow up on areas identified for further clarification;
      - Keep ongoing communication with the PI;
      - Take care of any question, situation or change related with AC, which may arise during the period that the protocol is active.

6. **Regulatory Knowledge and Support Core (RKS):**
   a. The Research Subject Advocate will:
      - Follow up on areas identified for further clarification;
      - Reconcile any document irregularities;
      - File the copy of the attendance record in the study file;
      - Keep ongoing communication with the PI for regulatory updates and changes to protocol requirements.

Attachment A

Study Initiation Meeting **AGENDA**

5 minutes	**Welcome and introductions**	**CRF Coordinator**
15 minutes	**Protocol review**	**Principal Investigator**
10 minutes	**Review of the CRF procedures**	**Head Nurse**
10 minutes	**Review of the TRCL procedures**	**Lab Manager**
10 minutes	**Review of the Administrative fee**	**Administrator**
10 minutes	**Review of updated regulatory documents on Investigator file**	**RSA**
5 minutes	**Summary/close the meeting**	**CRF Coordinator**