This form needs to be uploaded into e-prost under Study-Related Documents Section.

**STUDY INFORMATION:**

|  |  |
| --- | --- |
| **Institutional Review Board (IRB)#** |  |
| **Full Title of Study:** |  |
| **PI Name (Last, First):**   * **Office #:** * **Cell (recommended)** * **Email Address:** |  |
| **PI has privileges to perform the study at UHT** | Yes  No |
| **Study Coordinator Name (Last, First):**   * **Office #:** * **Cell (recommended)** * **E-Mail Address:** |  |

**STUDY DETAILS**

|  |  |
| --- | --- |
| **Study Type** | DRUG  DEVICE  BIOLOGIC  OBSERVATIONAL |
| **Name (s) of Drugs or Devices being investigated (if applicable)** | N/A |
| **Funding Source** | Industry Sponsored  Non-Industry Sponsored |
| **Sponsor Name** |  |
| **Does this study involve an IND(Investigational New Drug)/IDE (Investigational Device Exemption)?** | Yes  NO IND/IDE No. \_\_\_\_\_\_\_\_\_\_\_ |
| **If Yes,please provide the following IND / IDE information.** | Investigator’s Brochure/Product Labeling  Sponsor Reimbursement Package |
| **Are these products FDA approved?** | Yes  NO |
| **Who will provide the investigational product (drug, device)?** | Manufacturer Sponsor  Other (please specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Where will the drug/device/agent be stored?** | Location:  N/A |

|  |  |
| --- | --- |
| **Protocol Start Date** |  |
| **Protocol End Date** |  |
| **Department Name:** |  |
| **Study Activities Location/s at UHealth Tower** |  |
| **Study Activities Description (example: consenting, sample/tissue collection, drug administration, tests, subject interventions, measurements…etc)** |  |

**UHT CLINICAL SERVICES/RESOURCES REQUIRE** (Check services needed for study) **Or N/A**

**Nutrition Services** (i.e. food, education, etc.)

**Pharmacy** (i.e. storage, dispensing, temperature)

Please specify:

  **Nursing services** (i.e. vital signs, medication administration, urine collection, etc.)

Please specify:

**Radiology** (CT Scan, MRI, Ultrasound, etc.)

Please specify:

**Cardiology** (EKG, ECHO, etc.,)

Please specify:

**Pathology/Laboratory** (phlebotomy, specimen processing... etc.)

Please specify:

**Cath Lab**

**Other services**

Please specify:

**Comments**:

**If you have any questions or concerns please contact us via email:** [UHTresearch@miami.edu](mailto:UHTresearch@miami.edu) **or**

**telephone # 305- 243-1488 (Christopher Otero)**