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

The University Health Tower (UHT) Office of Research requires an approval by UHT Feasibility Research Committee (FRC). \*Observational studies may not warrant approval by FRC.

**STUDY INFORMATION:**

|  |  |
| --- | --- |
| Institutional Review Board (IRB)# |  |
| Full Title of Study: |  |
| PI Last Name, First Name/Degree |  |
| PI Office # |  |
| PI Cell (recommended) # |  |
| PI E-Mail Address |  |
| PI has privileges to perform the study at UHT | [ ]  YES [ ] NO |
| PI Department/Division/Specialty |  |
| List Co-PI and Sub investigators Last Name, First Name/Degrees |  |
| Study Coordinator (SC)Last Name, First Name |  |
| Study coordinator Office # |  |
| Study Coordinator Cell #(recommended) |  |
| Study Coordinator E-Mail  |  |
| Finance Contact (ex. ORA analyst)Last Name, First Name |  |
| Finance Contact office # |  |
| Finance Contact E-Mail Address |  |

**STUDY DETAILS**

|  |  |
| --- | --- |
| Study Type/Study Design (select all that apply) | [ ]  Drug [ ]  Device [ ]  Diagnostic[ ]  Biologic [ ]  Epidemiologic [ ]  Observational[ ]  Registry[ ]  Creating database[ ]  Therapeutic[ ]  Prospective [ ]  Blind [ ] Double blind [ ] Placebo controlled[ ]  other: |
| Stratification | [ ]  Randomized [ ] Not randomized |
| Phase of the Study |  [ ]  0 [ ]  1 [ ]  2 [ ] 3 [ ] 4   [ ]  other |
| Drugs or Devices being investigated  | Name:or[ ]  N/A |
| Funding Source | [ ]  Industry Sponsored [ ]  Grant Agency/Foundation/Government[ ] Other: |
| Sponsor/Manufacturer  | Name:[ ]  N/A |
| Does this study involve an IND(Investigational New Drug)/IDE (Investigational Device Exemption)? | [ ]  Yes [ ]  NO IND/IDE No:[ ]  N/A |
| **If Yes,** please provide the following IND / IDE information.  | [ ]  Investigator’s Brochure/Product Labeling[ ]  Sponsor Reimbursement Package |
| Are these products FDA approved?  |  [ ]  Yes [ ]  NO   [ ]  N/A |
| Who will provide the Investigational Product (drug, device)? | [ ] Manufacturer [ ] Sponsor [ ]  Physician/practice group[ ]  UHT[ ]  other (please specify): |
| Where will the drug/device/agent be stored? | Location:[ ]  N/A |

|  |  |
| --- | --- |
| Date Requested for Site Initiative Visit |   |
| Estimated Duration of Study  |   |
| Protocol Start /End Date |   |
| Number of UHT Subjects to be enrolled  |  |
| Will you need to recruit in the Emergency Department? |  [ ]  Yes [ ] No |

 **UHT SERVICES/RESOURCES REQUIRE Check services needed for study**)

 [ ]  Nutrition Services (i.e. food, education, etc.)

Please specify:

[ ]  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:

 [ ]  Other services:

Please specify:

|  |
| --- |
|  [ ]  **Inpatient, Regular (indicate the unit)**    Expected Length of Stay (LOS): Days  [ ]  **Inpatient:** **Admission for Research (indicate the unit)** Expected Length of Stay (LOS): Days |

 **What to Expect Next:**

* UHT Office of Research reviews **UHT Research Services/Resources Requested Form**

and request additional information as needed.

* UHT Office of Research communicates with the study team on the date of the Feasibility Research Committee (FRC).
* UHT Office of Research provides E-Prost ancillary approval upon completion of the Feasibility Review Committee (FRC).
* **UHT Office of Research issues an Approval Letter upon completion of all required steps:**

|  |
| --- |
| 1. IRB approved (study team notifies UHT Office of Research via email with the approval letter from IRB, WIRB or other private IRB)
2. Budget approved (Copy of the Fully Executed Agreement signed by PI needs to be sent to UHT Office of Research via email UHTresearch@miami.edu
3. Device Studies: Biomed to perform initial inspection and issued assessment report.
4. Staff on affected floors must be in-serviced on the research study and a copy must be submitted to UHT Office of Research UHTresearch@miami.edu

 I understand that I cannot start my study until the above steps are compete and I have received the UHT Letter of Approval\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_PRINCIPAL INVESTIGATOR (PLEASE PRINT AND SIGN) DATE |

**If you have any questions or concerns please contact us via email:** UHTresearch@miami.edu **or**

**tel # 305- 243-7412 (Halina Kusack)**