# NON-SENSITIVE STUDY ONLY

**VERSION DATE:**  Select date from drop-down

**LIST ALL EHC UNITS/CLINICS IN WHICH THE CLINICAL TRIAL IS EXPECTED TO TAKE PLACE:** [ ]  NA

TEC:  WCI:  EUH:  EUHM: ESJH:

EJCH:  EUOSH:  EWWH: ECC:  ESA:

EDH:  EHH:  ELTACH:  HSRB:  Ponce:

Hope:  WMRB:  PTC:  CRN:  CHOA:

GHS:  VA:  Other:

**Visit Type(s) as required by research protocol:** [ ] Inpatient/Observation/Overnight [ ] Outpatient [ ] Both

**IRB #:**

**Anticipated Start Date:** Select date from drop-down **Anticipated End Date:** Select date from drop-down

**BRIEF TITLE (as known by research participants):**

**PROTOCOL TITLE:**

**BRIEF SUMMARY OF STUDY:** *(include lay summary from consent)*

 **24 hour Emergency Contacts:** *(please include alternates)*

|  |  |  |  |
| --- | --- | --- | --- |
| **PI Name:** | **Email:**   | **Daytime #:**  | **Cell/Pager #:**  |
| **CRC Name:** | **Email:**  | **Daytime #:**  | **Cell/Pager #:**  |
| **CRC Name:**  | **Email:**  | **Daytime #:**  | **Cell/Pager #:**  |

**POTENTIAL SAFETY ISSUES:**

1. Describe clinical events or laboratory findings that require **immediate notification of the study investigator/team:**

****

1. Describe clinical procedures that are contraindicated or associated with increased risk in study participants:

****

1. Describe any important information for healthcare providers engaged in a healthcare encounter with this study participant:

****

 **EHC NURSING RESEARCH ACTIVITIES:** **[ ] Yes** **[ ] No** *(Check appropriate box if EHC Nurses and/or clinical staff expected to perform any research activities.* ***If yes, go to Q #4. If no, go to Q #9):***

1. Describe any required study medications/vaccines that EHC nurses and/or clinical staff will be asked to administer:

****

1. Describe any investigational treatments, procedures, or devices that EHC nurses and/or clinical staff will use:

****

1. Describe any additional data, vital signs, or labs that EHC nurses and/or clinical staff will be expected to collect or document that are not routine or routinely recorded in EeMR. Identify any EKGs or labs (PKs/pharmacokinetics) that will be required after hours (5 pm), weekends, and/or holidays:

****

1. Describe any additional research specific duties required of EHC nurses and/or clinical staff not mentioned above:

****

8. Select most appropriate box for training of EHC nurses and/or clinical staff:

[ ] Training not applicable, e.g. no EHC nursing and/or clinical staff research activities; OR

[ ]  In-services for EHC nursing and/or clinical staff have been scheduled; OR

[ ] Arrangements for training will be scheduled closer to study start date.

\**In-services for EHC nursing and/or clinical staff shall be done before EHC nursing and/or clinical staff will perform any research activities. Training should include probable side effects and drug interactions of investigational drugs, if applicable.*

**To access the Investigational Drug Data Sheet for probable side effects and drug interactions of investigational drugs, select “On Clinical Trial” in the EeMR banner bar. When the enrollment history box appears, select “Initial Protocol” to view the Investigational Drug Data Sheet and Clinical Research Key Points.**

**LABORATORY SERVICES** *(EML ONLY,* ***not*** *Emory Genetics Lab)*

1. Does this protocol require special labs or labs that require special processing to be performed by Emory Medical Laboratory (EML): **[ ] Yes [ ] No**

 *(Check appropriate box.* ***If yes, submit checklist directly to EML. If no, go to Q #10).***

 ***If routine labs per EML list, the EML checklist is not required.***

**RADIOLOGY AND IMAGING SCIENCES** *(excludes BITC or CSI)*

1. Does this protocol require services to be performed in the Emory Radiology Department **[ ] Yes [ ] No**

*(Check appropriate box.* ***If yes, submit checklist directly to Radiology.****)*

**\*\*When this form is complete, upload to eIRB *(for applicable drug, device, or interventional studies)*\*\***

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