**\*\*Bayview CRU TEMPLATE\*\***

**(The text statements in red are “prompts.” Delete red text upon completion of the form)**

**You *must* enter a response for each item and upload the form to eIRB Section 6 item 10**

**!!Forms with remaining red text will be returned for revision!!**

**High Risk Review Committee (HRRC) Information Collection Form**

Your protocol requires supplemental pre-review by a high-risk review committee.

1**) Please list the drug(s), product(s) or activity that you led you to select the box in the IRB application. Provide details about the *emergent* risks associated with the drug(s) product(s) and/or research activity and describe the likelihood of those risks.**

Example: Drug X has a 2% chance of causing an allergic or infusion related reaction.

If applicable you can consider inserting “The likelihood of an infusion-related reaction to (drug name) may be limited due to the (insert prophylaxis) prophylaxis that will be given before the infusions.

Example: Insertion of an arterial line may cause:

Example: Insertion of the XX device has the following risks XX with a X% likelihood of occurrence.

**2) Confirm that the drug administration or activity will only occur in the BV CRU.**

**3) Specify the time the administration of drug(s)/product(s) or conduct of the activity will occur.**

**4) List the person(s) who will be present during the drug/product administration or activity, their qualifications to respond to an emergency, their relevant credentials/institutional privileges, and the period of time they will be present to attend to the participant.**

*EXAMPLE:* For the duration of the drug administration (or duration of the activity) and for 1 hour post the first three drug administrations, the PI, covering MD (provide name) or Advanced Practice Provider (provide name) will be present to lead any necessary response to an adverse event. For the remaining study drug administrations, the PI or covering provider will be on campus and physically available to respond to assess and treat an adverse event if required.

As required, all of these MDs (or Advanced Practice Providers) are credentialed, have institutional privileges, **and have the ability to readily asses and respond to a reaction to the study medication**.

***Insert Study Team Member details:***(If you have study team members that will administer the study product and or attend to participants please describe the details required in question 5 for each of these study team members)

EXAMPLE:

Liz Martinez RN, BSN/ BLS Certified / Credentialed RN JHU/ administer product and monitor for 3 hours

The nursing staff in the clinical research unit (RNs) are trained and credentialed to perform drug administration. The nurses on the CRU are BLS certified and will attend to the participant during the infusion and for (*insert required post dosing observation period.*)

**5) Outline the specific procedures that will be followed in the event of an emergency.**

Urgent assessment and supportive care will be provided by the nursing staff on the Bayview CRU.

The PI (or other JH Institutionally credentialed MD/ Advanced Practice Provider assigned by PI to cover) will order medical intervention as deemed appropriate. (Insert medications and/or interventions that may be needed for your study) EXAMPLE: This may include administration of the following medications, oxygen, postural changes, and administration of fluids.

The following rescue medications may be used and will obtained from the pharmacy along with the study drug for use in case of a reaction/adverse event (if they are not available on the unit- see unit list below): (insert appropriate medications for your study.)

If a reaction or adverse event cannot be managed (using the measures above) or the patient’s condition warrants, 911 will be called and the participant transferred by ambulance to the Bayview Emergency Room for treatment.

**6) Describe the emergency equipment and medications that are readily available, their specific location and assure their availability to the research team.**

The Bayview CRU maintains the following emergency equipment and medications

AED in the hallway across from the CRU door entrance, Portable Oxygen tank in front hallway in CRU by file cabinet and IV fluids

Emergency drug box, airway box, oxygen masks, cannula and tubing, portable suction machine are on the cart in the hallway in front of CRU Nurses’ Workroom.

THe emergency drug box includes:

3 Adenosine 6mg/2ml vial

1 Albuterol Sulfate 200inh (ProAir) 200inh

2 Amiodarone 500mg/ml, 3ml vial

1 Atropine 0.1 mg/ml, 10ml syringe

2 Dextrose 50%, 50ml syringe

1 Diphenhydramine 50mg/ml, 1 ml vial

1 Dopamine 400mg/250ml pre-mixed bag

2 Epinephrine 1mg (1:1,000), 1ml vial

3 Epinephrine 1mg (1:10,000), 10ml syringe

2 Lidocaine 2%, 100mg/ml/5ml syringe

2 Magnesium sulfate 4 gm/100ml

2 Methylprednisolone 125mg/2ml vial

1 Naloxone 0.4 mg/ml