**\*\*JH 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 (HRCC) 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) Specify the CRU(s) where the drug(s) product(s) will be administered or the activity conducted.**

The JH CRU’s include: Inpatient Adult Clinical Research Unit, Inpatient Pediatric Clinical Research Unit, Outpatient Adult Research Unit, Outpatient Pediatric Clinical Research Unit- insert all that apply to your study

**3) Will the administration of drug(s)/product(s) or conduct of the activity occur during usual clinic hours?**

**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:

* Todd Brown MD/Credentialed JH/BVMC/present for administration period and 1 hour post dose
* 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 CRU.

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

The following rescue medications may be used and will be 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 lists) (insert appropriate medications for your study /or state: All medications that may be used are available on the unit.)

If the reaction or adverse event cannot be managed (using the measures above) or the patient’s condition warrants, the appropriate Rapid Response Team will be activated to respond to the Unit.

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

The JH Campus CRUs are equipped with standard hospital emergency carts and emergency drug boxes as well as a defibrillator, oxygen, suction and IV fluids. These items are located centrally on the unit and maintained by the CRU staff per hospital policy.

The Emergency Drug Box Contains:

* Atropine for injection
* Calcium Chloride for injection
* Dextrose for injection
* Epinephrine for injection
* Lidocaine for injection
* Sodium Bicarbonate for injection
* Adenosine for injection
* Amiodarone for injection
* Hydrocortisone for injection
* Magnesium Sulfate for injection
* Naloxone for injection
* Norepinephrine for injection
* Phenylephrine for injection

In addition, the inpatient CRUs and the outpatient PCRU have a **pyxis** (medication dispensing device) containing standard medications that may be used to treat an emergent event.

**ONLY INCLUDE LIST FOR THE CRU’s APPLICABLE TO YOUR STUDY- Delete others**

**Outpatient Adult medications include:**

* Albuterol 2.5mg/3ml Nebule
* Cetrizine (Zyrtec) 10mg tablet
* Diphenhydramine (Benadryl) 50mg/1ml vial
* Diphenhydramine (Benadryl) 50mg tablet
* Epinephrine for Anaphylaxis 1mg/1ml injection
* Epinephrine IM EpiPen (0.3mg) 0.3mg/0.3ml
* Famotidine (Pepcid) 20mg tablet
* Ondansetron (zofran) disintegrating 4mg tablet
* Hydrocortisone 1% 30g cream
* Lidocaine 4% topical cream 5g cream
* Methylprednisolone (Solu-Medrol) 125mg/2 ml vial
* Prednisone tablet 20mg
* Hydrocortisone succinate (Solu-cortef) 100mg injection
* Acetaminophen
* Ibuprophen
* Aspirin chewable tablet
* Nitroglycerine SL tablet .4mg

**Outpatient Pediatric CRU medications include:**

* Albuterol 0.083% 2.5mg/3ml Nebule
* Albuterol HFA W/Counter Inhaler
* Cetrizine (Zyrtec) 5mg/5ml cup
* Diphenhydramine (Benadryl) 50mg/1ml vial
* Diphenhydramine (Benadryl) Elixir 25mg/10 ml cup
* Epinephrine for Anaphylaxis 1mg/1ml injection
* Epinephrine IM EpiPen (0.3mg) 0.3mg/0.3ml
* Epinephrine IM EpiPenJr (0.15) 0.15mg/1ml
* Famotidine (Pepcid) 20mg tablet
* Hydrocortisone 1% 30g cream
* Ipratropium Brom. (Atrovent) 17mcg/inh 12.9g inhaler
* Lidocaine 4% topical cream 5g cream
* Methylprednisolone (Solu-Medrol) 40mg/1 ml vial
* Ondansetron (zofran) disintegrating 4mg tablet
* Prednisolone sodium Phos 15mg/5ml cup
* Prednisone 10mg tablet

**Inpatient PCRU medications include:**

* Albuterol 0.083% 2.5mg/3ml Nebule
* Albuterol HFA W/Counter Inhaler
* Diphenhydramine (Benadryl) 50mg/1ml vial
* Diphenhydramine (Benadryl) Elixir 25mg/10 ml cup
* Epinephrine for Anaphylaxis 1mg/1ml injection
* Epinephrine IM EpiPen (0.3mg) 0.3mg/0.3ml
* Epinephrine IM EpiPenJr (0.15) 0.15mg/1ml
* Lidocaine 4% topical cream 5g cream
* Ondansetron (zofran) disintegrating 4mg tablet

**Inpatient Adult CRU medications include:**

* Albuterol 0.083% 2.5mg/3ml Nebule
* Albuterol HFA W/Counter Inhaler
* Diphenhydramine (Benadryl) 50mg/1ml vial
* Diphenhydramine (Benadryl) capsule 25mg
* Famotidine (Pepcid) 20mg tablet
* Ipratropium Brom. (Atrovent) solution for nebulization
* Lidocaine 4% topical cream 5g cream
* Ondansetron (zofran) disintegrating 4mg tablet
* Prednisone 20mg tablet