**\*\* 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 X

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

**2) Name the building(s) and room number(s) where the drug(s) product(s) will be administered or the activity conducted.**

**3) Is the space where you will be administering the drug(s)/product(s) or performing the activity a *clinical space* where routine *health care* is provided?**

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

**5) 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 and for 1 hour post the first three drug administrations, the PI, covering MD or Advanced Practice Provider will be present to lead any necessary response to a reaction. 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

Todd Brown MD ACLS Certified JHM and Bayview Privileges on site for administration +1hr

**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 PI (or other Institutionally credentialed MD/ Advanced Practice Provider assigned by PI to cover) will order medical intervention as deemed appropriate. (outline medications and/or interventions that apply) EXAMPLE: This may include administration of, oxygen, postural changes, IV fluids and or these medications LIST MEDICATIONS.

If the reaction or adverse event cannot be managed (using the measures above) or the patient’s condition warrants, (specify next action. Is there a rapid response team for this area, would you have to call 911 and transport? Detail how that action is activated and managed**. Details are required**.)

**6) Describe the emergency equipment and medications that will be readily available, their specific location and assure their availability to the research team. If you will be obtaining these items and bringing them to the site describe the plan for that.**

**Be very specific:**

Example: The clinic is equipped with standard 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 clinic staff per hospital policy. The research team will have access to these if necessary.

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.

Example: The area has a defibrillator in the east corridor. The study team will obtain the following medications from the pharmacy along with the study drug/product and have them available at the time of administration: LIST MEDS.