



**Center for Clinical and  
Translational Research  
Standard Operating Procedure**



Section: **Clinical Research Center**

Date Created: **June 12, 2019**

Title: **Allergy/Hypersensitivity Management**

Version Date: **January 1, 2023**

SOP Number: **CO42**

**PURPOSE:** The purpose of this standard operating procedure (SOP) is to outline the steps taken if an allergy/hypersensitivity occurs in the Clinical Research Center (CRC).

**SCOPE:** This SOP applies to all site personnel involved in the care and coordination of clinical research subjects who incur an allergy/hypersensitivity while in the CRC.

**PERSONNEL RESPONSIBLE:** Clinical Research Nurse and/or any other research study personnel that may discover a subject in an allergy/hypersensitivity reaction.

**DEFINITIONS:**

**Allergy/Hypersensitivity:**

1. Allergy or hypersensitivity reactions are excessive reactions to an allergen; severity ranges from mild allergy to severe systemic reactions leading to anaphylactic shock.
2. Infusion related reactions may present with symptoms similar to allergy/hypersensitivity reactions but differ in underlying pathophysiology. Both types of reactions are treated in the same manner.
3. Anaphylactic reactions are unpredictable, immediate systemic reaction within seconds to minutes following administration of a foreign protein (allergen), resulting in a medical emergency to prevent respiratory or cardiac failure.

**PROCEDURES:**

1. Upon recognition of an emergent allergy/hypersensitivity/infusion related situation the research nurse may immediately implement the protocol for treatment outlined in this SOP.
  - Treatment will not be delayed to obtain a physician's order.
2. Concurrent with treatment the Principal Investigator, CRC Medical Director, Research Nurse Manager is notified of the emergent situation and are consulted for subsequent treatment and management orders.
3. All allergy/hypersensitivity/infusion related reactions, regardless of medication, blood product or other potential allergen involved will be treated utilizing the protocols outlined in **Tables A (Adult Patients) or B (Pediatric Patients)** unless provider orders defining a preferred treatment plan are present in the medical record at the time of the episode.
4. Table A (Adult Patients) and Table B (Pediatric Patients) are posted in Procedure Rooms 3 and 4 of the CRC UT CRU.
5. Vital signs will be assessed at least every 15 minutes until stable for at least 30 minutes.
6. Treatment will continue until the patient has been stable for at least 30 minutes, is transferred to the emergency department as deemed appropriate by the investigator



**Center for Clinical and  
Translational Research  
Standard Operating Procedure**



Section: **Clinical Research Center**

Date Created: **June 12, 2019**

Title: **Allergy/Hypersensitivity Management**

Version Date: **January 1, 2023**

SOP Number: **CO42**

and/or medical emergency team, or the patient is deemed stable by a licensed physician or advanced practice provider.

**ASSOCIATED FORMS:**

Adult Table A

Pediatric Table B

**RESOURCES:**

Nebraska Medicine:

[EC31 – Medical Emergencies Protocol](#)

[CP RX14 Allergy/Hypersensitivity Management](#)

**Department Approval**

Signed Serena Gaines  
Research Nurse Manager

Signed: 9/3/2025

Signed [Signature]  
Assistant Vice Chancellor for Clinical Research

Signed: 9/2/2025

## TABLE A ADULT

Table A – Adult Patients Allergy/Hypersensitivity Management Protocol (Adult)

Grade	New Symptom	Management	Administer Medications
1	<ul style="list-style-type: none"> <li>Transient rash</li> <li><math>\pm</math> 1 degree Celsius temperature change from baseline</li> </ul>	<ol style="list-style-type: none"> <li>1. <b>Stop drug infusion (remove IV tubing) and/or remove allergen.</b></li> <li>2. Administer medications (see next column)</li> <li>3. Notify primary provider and/or authorizing provider/designee (and pharmacist if needed)</li> <li>4. Monitor BP, HR, RR, Temp at least every 15 minutes</li> <li>5. If OK with provider restart IV infusion at half the previous rate once symptoms have improved or resolved</li> <li>6. If symptoms reappear notify provider and stop infusion.</li> </ol>	Diphenhydramine 50 mg IVP x1
2	<ul style="list-style-type: none"> <li>Hives or itching</li> <li>Flushing</li> <li>Fever greater than or equal to 38°C (100.4°F)</li> <li>Asymptomatic bronchospasm               <ul style="list-style-type: none"> <li>mild wheezing without dyspnea, hypoxia, or difficulty swallowing</li> </ul> </li> <li>Rigors (shivers)</li> </ul>	<ol style="list-style-type: none"> <li>1. <b>Stop drug infusion (remove IV tubing) and/or remove allergen.</b></li> <li>2. Oxygen as needed to maintain sats greater than 90%</li> <li>3. Administer medications (see next column)</li> <li>4. Notify primary provider and/or authorizing provider/designee (and pharmacist if needed)</li> <li>5. Monitor BP, HR, RR, Temp at least every 15 minutes</li> </ol>	0.9% NaCl IV at 100 ml/hr + Diphenhydramine 50 mg IVP x1 + Hydrocortisone 100 mg IVP x1 OR Methylprednisolone 125 mg IVPx1
3	<ul style="list-style-type: none"> <li>Dyspnea or hypoxia (+/- wheezing, difficulty swallowing, or hives)</li> <li>Fever greater than or equal to 38°C (100.4°F)</li> <li>Edema/angioedema swelling beneath the skin most often around the lips and eyes</li> <li>Hypotension (decrease in systolic or diastolic blood pressure greater than 30 mm Hg)</li> <li>Arrhythmia or irregular heart rate</li> <li>Rigors (shivers)</li> </ul>	<ol style="list-style-type: none"> <li>1. <b>Stop drug infusion (remove IV tubing) and/or remove allergen.</b></li> <li>2. <b>Call RRT</b> or activate emergency response based on clinic/departmental policy.</li> <li>3. Oxygen as needed to maintain sats greater than 90%.</li> <li>4. Administer medications (see next column)</li> <li>5. Notify primary and/or authorizing provider/designee</li> <li>6. Monitor BP, HR, RR, Temp at least every 15 minutes.</li> </ol>	0.9% NaCl IV at 100 ml/hr + Diphenhydramine 50 mg IVP x1 + Hydrocortisone 100 mg IVP x1 OR Methylprednisolone 125 mg IVP x1 + Epinephrine <b>1 mg/mL</b> 0.3 mg (0.3 mL) <b>IM</b> x1 in anterior-lateral thigh. May repeat same dose IM x1 in 10-15 minutes if patient still symptomatic & no additional provider orders yet received
4	<ul style="list-style-type: none"> <li>Anaphylaxis (rapid onset of systemic respiratory/cardiac response/collapse)</li> </ul>	<ol style="list-style-type: none"> <li>1. <b>Stop drug infusion (remove IV tubing) and/or remove allergen.</b></li> <li>2. <b>Call Code Blue</b> or activate emergency response based on clinic/departmental policy.</li> <li>3. Administer medications (see next column)</li> <li>4. Notify primary and/or authorizing provider/designee</li> <li>5. Monitor BP, HR, RR, Temp at least every 15 minutes.</li> </ol>	Diphenhydramine 50 mg IVP x1 + Hydrocortisone 100 mg IVP x1 OR Methylprednisolone 125 mg IVP x1 + Epinephrine <b>1 mg/mL</b> 0.3 mg (0.3 mL) <b>IM</b> x1 in anterior-lateral thigh. May repeat same dose IM x1 in 10-15 minutes if patient still symptomatic & no additional provider orders yet received

**NOTE:** The IM route may be used instead of the IV route for diphenhydramine and hydrocortisone when IV access is not available; methylprednisolone should NOT be administered IM due to high incidence of subcutaneous atrophy.

**NOTE:** Drug shortages may impact availability of certain formulations and/or medications

## TABLE B Pediatric

Table B – Pediatric Patients Allergy/Hypersensitivity Management Protocol (Pediatric)

Grade	New Symptom	Management	Administer Medications						
1-3	<ul style="list-style-type: none"><li>Transient rash, hives, flushing, itching</li><li><math>\pm 1</math> degree Celsius temperature change from baseline or fever greater than or equal to 38°C (100.4°F)</li><li>Difficulty breathing (dyspnea, hypoxia or difficulty swallowing)</li><li>Rigors (shivers)</li><li>Edema/angioedema – swelling beneath the skin most often around the lips and eyes</li><li>Hypotension:<ul style="list-style-type: none"><li>Neonates-- up to 28 days, Systolic BP less than 60mmHG</li><li>Infant-- up to 1 yr, Systolic BP less than 70mmHG</li><li>Child-- 1-12 yo, Systolic BP less than 70mmHG + (2 x age)</li></ul></li><li>Arrhythmia or irregular heart rate</li></ul>	<ol style="list-style-type: none"><li><b>Stop drug infusion (remove IV tubing) and/or remove allergen.</b></li><li>If any respiratory symptoms are present, start oxygen and <b>call for Pediatric RRT, or</b> activate emergency response based on clinic/departamental policy</li><li>Administer medications (see next column)</li><li>Notify primary and/or authorizing provider/designee.</li><li>Monitor BP, HR, RR, Temp at least every 15 minutes.</li></ol>	<p>Diphenhydramine 1 mg/kg mg IVP x1 (max dose 50 mg IVP x1)</p> <p>+</p> <p>0.9% NaCl IV at 20 mL/kg/hr up to 1000 mL total</p> <p>↓</p> <p>If symptoms progress or do not improve after diphenhydramine give</p> <p>Hydrocortisone 1 mg/kg IVP x1 (max dose 100 mg IVP x1)</p> <p>↓</p> <p>Epinephrine if directed to do so by provider or if rapid progression of symptoms after all of the above (dose &amp; product based on weight)</p> <table><tr><td>Less than 10 kg</td><td><b>1 mg/mL Vial</b> 0.01 mg/kg = 0.01 mL/kg <b>IM</b> x1</td></tr><tr><td>10-29 kg</td><td><b>1 mg/mL Jr. Pen</b> 0.15 mg <b>IM</b> x1</td></tr><tr><td>30 kg or greater</td><td><b>1 mg/mL Adult Pen</b> 0.3 mg <b>IM</b> x1</td></tr></table>	Less than 10 kg	<b>1 mg/mL Vial</b> 0.01 mg/kg = 0.01 mL/kg <b>IM</b> x1	10-29 kg	<b>1 mg/mL Jr. Pen</b> 0.15 mg <b>IM</b> x1	30 kg or greater	<b>1 mg/mL Adult Pen</b> 0.3 mg <b>IM</b> x1
Less than 10 kg	<b>1 mg/mL Vial</b> 0.01 mg/kg = 0.01 mL/kg <b>IM</b> x1								
10-29 kg	<b>1 mg/mL Jr. Pen</b> 0.15 mg <b>IM</b> x1								
30 kg or greater	<b>1 mg/mL Adult Pen</b> 0.3 mg <b>IM</b> x1								
4	<ul style="list-style-type: none"><li>Anaphylaxis (rapid onset of systemic respiratory/cardiac response/collapse)</li></ul>	<ol style="list-style-type: none"><li><b>Stop drug infusion (remove IV tubing) and/or remove allergen</b></li><li><b>Call Pediatric Code Blue or</b> activate emergency response based on clinic/departamental policy</li><li>Administer medications (see next column)</li><li>Notify primary and/or authorizing provider/designee</li><li>Monitor BP, HR, RR, Temp at least every 15 minutes</li></ol>	<p>Diphenhydramine 1 mg/kg mg IVP x1 (max dose 50 mg IVP x1)</p> <p>+</p> <p>Hydrocortisone 1 mg/kg IVP x1 (max dose 100 mg IVP x1)</p> <p>+</p> <p>Epinephrine IM (dosing based on table provided under grade 1-3 reactions)</p>						

**NOTE:** The IM route may be used instead of the IV route for diphenhydramine and hydrocortisone when IV access is not available

**NOTE:** Drug shortages may impact availability of certain formulations and/or medications