



**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 the Procedure Room 4 of the CRC.



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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: 2/9/2023

Signed [Signature]
Assistant Vice Chancellor for Clinical Research

Signed: 2/7/2023

CO42

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"> • Transient rash • \pm 1 degree Celsius temperature change from baseline 	<ol style="list-style-type: none"> 1. Stop drug infusion (remove IV tubing) and/or remove allergen. 2. Administer medications (see next column) 3. Notify primary provider and/or authorizing provider/designee (and pharmacist if needed) 4. Monitor BP, HR, RR, Temp at least every 15 minutes 5. If OK with provider restart IV infusion at half the previous rate once symptoms have improved or resolved 6. If symptoms reappear notify provider and stop infusion. 	Diphenhydramine 50 mg IVP x1
2	<ul style="list-style-type: none"> • Hives or itching • Flushing • Fever greater than or equal to 38°C (100.4°F) • Asymptomatic bronchospasm <ul style="list-style-type: none"> ○ mild wheezing without dyspnea, hypoxia, or difficulty swallowing • Rigors (shivers) 	<ol style="list-style-type: none"> 1. Stop drug infusion (remove IV tubing) and/or remove allergen. 2. Oxygen as needed to maintain sats greater than 90% 3. Administer medications (see next column) 4. Notify primary provider and/or authorizing provider/designee (and pharmacist if needed) 5. Monitor BP, HR, RR, Temp at least every 15 minutes 	0.9% NaCl IV at 100 ml/hr + Diphenhydramine 50 mg IVP x1 + Hydrocortisone 100 mg IVP x1
3	<ul style="list-style-type: none"> • Dyspnea or hypoxia (+/- wheezing, difficulty swallowing, or hives) • Fever greater than or equal to 38°C (100.4°F) • Edema/angioedema swelling beneath the skin most often around the lips and eyes • Hypotension (decrease in systolic or diastolic blood pressure greater than 30 mm Hg) • Arrhythmia or irregular heart rate • Rigors (shivers) 	<ol style="list-style-type: none"> 1. Stop drug infusion (remove IV tubing) and/or remove allergen. 2. Call RRT or follow the similar emergency procedure. 3. Oxygen as needed to maintain sats greater than 90%. 4. Administer medications (see next column) 5. Notify primary and/or authorizing provider/designee 6. Monitor BP, HR, RR, Temp at least every 15 minutes. 	0.9% NaCl IV at 100 ml/hr + Diphenhydramine 50 mg IVP x1 + Hydrocortisone 100 mg IVP x1 + Epinephrine 1 mg/mL 0.3 mg (0.3 mL) IM 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"> • Anaphylaxis (rapid onset of systemic respiratory/cardiac response/collapse) 	<ol style="list-style-type: none"> 1. Stop drug infusion (remove IV tubing) and/or remove allergen. 2. Call Code Blue or follow the similar emergency procedure. 3. Administer medications (see next column) 4. Notify primary and/or authorizing provider/designee 5. Monitor BP, HR, RR, Temp at least every 15 minutes. 	Diphenhydramine 50 mg IVP x1 + Hydrocortisone 100 mg IVP x1 + Epinephrine 0.1 mg/mL 0.01 mg/kg IV (max dose 1 mg). The IM route can be used if no IV access.

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 of medications

CO42

TABLE A ADULT**Table B – Pediatric Patients****Allergy/Hypersensitivity Management Protocol (Pediatric)**

Grade	New Symptom	Management	Administer Medications						
1-3	<ul style="list-style-type: none"> • Transient rash, hives, flushing, itching • \pm 1 degree Celsius temperature change from baseline or fever greater than or equal to 38°C (100.4°F) • Difficulty breathing (dyspnea, hypoxia or difficulty swallowing) • Rigors (shivers) • Edema/angioedema – swelling beneath the skin most often around the lips and eyes • Hypotension: <ul style="list-style-type: none"> ○ Neonates-- up to 28 days, Systolic BP less than 60mmHG ○ Infant-- up to 1 yr, Systolic BP less than 70mmHG ○ Child-- 1-12 yo, Systolic BP less than 70mmHG + (2 x age) • Arrhythmia or irregular heart rate 	<ol style="list-style-type: none"> 1. Stop drug infusion (remove IV tubing) and/or remove allergen. 2. If any respiratory symptoms are present, start oxygen and call for Pediatric RRT, or the similar emergency procedure. 3. Administer medications (see next column) 4. Notify primary and/or authorizing provider/designee. 5. Monitor BP, HR, RR, Temp at least every 15 minutes. 	<p>Diphenhydramine 1 mg/kg mg IVP x1 (max dose 50 mg IVP x1)</p> <p style="text-align: center;">+</p> <p>0.9% NaCl IV at 20 mL/kg/hr up to 1000 mL total</p> <p style="text-align: center;">↓</p> <p>If symptoms progress or do not improve after diphenhydramine give Hydrocortisone 1 mg/kg IVP x1 (max dose 100 mg IVP x1)</p> <p style="text-align: center;">↓</p> <p>Epinephrine if directed to do so by provider or if rapid progression of symptoms after all of the above (dose & product based on weight)</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <tr> <td style="text-align: center;">Less than 10 kg</td> <td style="text-align: center;"><u>1 mg/mL Vial</u> 0.01 mg/kg = 0.01 mL/kg IM x1</td> </tr> <tr> <td style="text-align: center;">10-29 kg</td> <td style="text-align: center;"><u>1 mg/mL Jr. Pen</u> 0.15 mg IM x1</td> </tr> <tr> <td style="text-align: center;">30 kg or greater</td> <td style="text-align: center;"><u>1 mg/mL Adult Pen</u> 0.3 mg IM x1</td> </tr> </table>	Less than 10 kg	<u>1 mg/mL Vial</u> 0.01 mg/kg = 0.01 mL/kg IM x1	10-29 kg	<u>1 mg/mL Jr. Pen</u> 0.15 mg IM x1	30 kg or greater	<u>1 mg/mL Adult Pen</u> 0.3 mg IM x1
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4	<ul style="list-style-type: none"> • Anaphylaxis (rapid onset of systemic respiratory/cardiac response/collapse) 	<ol style="list-style-type: none"> 1. Stop drug infusion (remove IV tubing) and/or remove allergen 2. Call Pediatric Code Blue or the similar emergency procedure. 3. Administer medications (see next column) 4. Notify primary and/or authorizing provider/designee 5. Monitor BP, HR, RR, Temp at least every 15 minutes 	<p>Diphenhydramine 1 mg/kg mg IVP x1 (max dose 50 mg IVP x1)</p> <p style="text-align: center;">+</p> <p>Hydrocortisone 1 mg/kg IVP x1 (max dose 100 mg IVP x1)</p> <p style="text-align: center;">+</p> <p>Epinephrine 0.1 mg/mL 0.01 mg/kg = 0.1 mL/kg IVP x1 (If IV route unavailable and IM dosing is needed see above Epinephrine table for dosing)</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 of medications