Center for Clinical and Translational Research Standard Operating Procedure

Section: **Clinical Research Center**
Date Created: **July 14, 2023**
Title: **Monoclonal Antibodies Administration**
Version Date: **January 1, 2025**
SOP Number: **CO05**

PURPOSE: The purpose of this standard operating procedure (SOP) is to enumerate the steps required for administration of investigational monoclonal antibodies in the Clinical Research Center (CRC), Clinical Research Units (CRUs).

SCOPE: This SOP applies to all site personnel involved in the care and coordination of clinical research subjects who are receiving an investigational monoclonal antibody product in a CRC CRU.

PERSONNEL RESPONSIBLE: Clinical research nurse(s) and/or any other research study personnel that may be involved in study drug administration of a monoclonal antibody in a CRC CRU.

DEFINITIONS:
Monoclonal Antibody (mAb): Laboratory-produced molecules engineered to serve as substitute antibodies that can restore, enhance, or mimic the immune system's attack on certain cells to help fight a disease.
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:
CRC Staff:

1. All CRC research nurses will be trained on medication administration, based on Nebraska Medicine policy (Med-02), and have documentation of such training prior to administering any IP in any CRC CRU. All CRC research nurses will review and understand CRC SOP CO42 - Allergy and Hypersensitivity, before completing any IP administration in a CRC CRU. A minimum of two nurses will be available for each IP administration.

2. Based on Oncology Nursing Society (2020) recommendations, CRC research nurses will be trained on infusion procedures, drug/dose verification procedures, monitoring considerations based on the protocol, anticipated side effects based on the protocol, and procedures for safe handling and disposal based on the protocol for mAb administration. Training on these topics is provided by the clinic and protocol sponsor (Bayer, 2019).

Study Intake:

1. All studies requesting nursing services for monoclonal antibody administration will be reviewed by the Research Nurse Manager and Medical Director of the Clinical Research Center for safety considerations prior to approval.
    a. The first dose, or high-risk doses, may be required to be given in the Fred & Pamela Buffet Cancer Center Infusion Center at the discretion of the CRC Medical Director.
2. All Principal Investigators (PI) will review CRC SOP CO42 prior to monoclonal antibody administration for their study in a CRC CRU. This review will be documented with a signature from the PI on a copy of the SOP.

Prior to Appointments:

1. Prior to accepting the clinic invite, CRC administrative staff will confirm availability of the study investigator on the day and time of request.
2. Once confirmation is obtained, the clinic appointment can be scheduled.
    a. Include ‘Monoclonal Antibody’ in clinic scheduling notes.
3. CRC research nurse to verify emergency medication box and supplies prior to appointment to have at patient bedside. Bedside emergency medication box will include, but not limited to, IV Hydrocortisone, IV Diphenhydramine, and an Epi-Pen (provided free of cost to the clinic by pharmacy).
    a. CRC research staff will check expiration dates and inclusion of all administration supplies.
4. Study investigator or team member (with investigator sign off) will utilize CRC Smart Set to order emergency medications when placing orders prior to the study visit. Study team members will be responsible for releasing the order. If this is not complete, CRC SOP CO42 will be utilized for administration of emergency medications.

During Appointments:

1. The study protocol will be followed.
2. Bedside emergency medication kit will be placed at the bedside before any mAb administration processes begin.
3. If gauge is not noted in the protocol, place a 16-, 18-, 20-, or 22- gauge peripheral intravenous (IV) catheter in a competent vein. For high-risk infusion days, a minimum of a 20- gauge IV is recommended.
4. If noted in the protocol or ordered, pre-medicate the subject at least 30 minutes prior to administration of IP.
5. A two-nurse double check is required prior to administration. The expectation is that CRC research nurses review the 5 rights of administration independently.
6. Complete IP administration per protocol or Nebraska Medicine policy and training. Infusion start and stop times will be documented per study protocol.
7. CRC research nurse will remain at beside for first 15 minutes of any high-risk infusion.
8. Once administration of an IV infusion product is complete, flush the product with at least 30 mL normal saline, unless otherwise noted in the study protocol.
9. Temperature, pulse, respiration rate, blood pressure, and Sp02 will be taken per protocol, prior to administration, 15 minutes into any infusion, post-administration, and at the discretion of medical staff.
10. If a reaction occurs, staff will immediately stop administration, begin the allergy/hypersensitivity protocol, and call the study investigator. If the reaction does not subside, or patient develops signs or symptoms of dyspnea or hypoxia, a Medical Emergency Team (MET) will be called per CRC policy EP01 and Nebraska Medicine policy MS17.
11. If patient develops significant hyper or hypotension, or reports chest pain, the patient will be sent to the Emergency Department via the MET.

After Appointments:

1. All subjects will be monitored per protocol. If protocol does not have a monitoring period, a monitoring period may be required at the discretion of the Investigator, study staff, or CRC clinical staff. Temperature, pulse, respiration rate, blood pressure, and Sp02 will be obtained prior to subject dismissal. Concerning assessments will be communicated to the study investigator for an assessment prior to subject dismissal.

Contact Information:

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RESOURCES:

Nebraska Medicine:

CP_RX14 Allergy/Hypersensitivity Management
MS17 Activation of Hospital Emergency Response Teams (HERT) (Code Blue, Rapid Response Team, Medical Emergency Team)
Med-02 Medication Administration
Med-07, Med-10, Med-11, Med 16, Med, 17, Med-18, Med-21, Med-22, Med-23, Med-26 Administration of Medication
SOP CO42 – Allergy Hypersensitivity Management
SOP EP01 – Medical Emergency

Other:

Administration for Strategic Preparedness and Response. (2021, August 17). COVID-19 Monoclonal Antibody (mAb) Checklist: Subcutaneous and Intravenous Administration

Bayer, V. (2019). An overview of monoclonal antibodies. *Seminars in Oncology Nursing*, *35*(5), 1-8. https://doi.org/10.1016/j.soncn.2019.08.006

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Mullard, A. (2021). FDA approves 100th monoclonal antibody product. *Nature Reviews*, *20*(7), 491-495. https://doi.org/10.1038/d41573-021-00079-7

Oncology Nursing Society. (2020, December). *ONS recommendations for administration of monoclonal antibodies for COVID-19 positive patients.* Oncology Nursing Society. https://www.ons.org/sites/default/files/2020-12/ONS_Recommendations_Administration_MonoclonalAntibodies_COVID19.pdf

Vogel, W. H. (2010). Infusion reactions: Diagnosis, assessment, and management. *Clinical Journal of Oncology Nursing, 14*(2), 10-21. https://doi.org/10.1188/10.CJON.E10-E21

Department Approval

Signed Serena Gaines Signed: 12/31/2024

Research Nurse Manager

Signed Signed: 12/31/2024

Assistant Vice Chancellor for Clinical Research