



Campus Administrative Policy

Policy Title: Utilization of University of Colorado’s Research Pharmacy Services

Policy Number: 6009 Functional Area: Research

Effective: July 1, 2021
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Supersedes: N/A - New Policy

Approved by: Donald M. Elliman, Jr
Chancellor, University of Colorado Anschutz Medical Campus

Prepared by: Office of Regulatory Compliance
Reviewing Office: Office of Regulatory Compliance
Responsible Officer: Vice Chancellor of Research

Applies to: CU Anschutz Medical Campus

A. INTRODUCTION

The University of Colorado Anschutz Medical Campus (CU Anschutz) has established this policy to ensure that all investigational products used in clinical research conducted by CU Anschutz faculty and staff comply with Food and Drug Administration requirements and United States Pharmacopeial standards: USP chapters <795> and <797> provide specific guidance for non-sterile and sterile compounding, respectively. More recently, USP <800> regulations address compounding considerations for hazardous and nonhazardous medications.

The CU Anschutz Research Pharmacy serves as a campus-wide service center to handle all aspects of product management for drugs and biologics used in clinical research to facilitate operational compliance when hospital pharmacy services are not available.

B. POLICY STATEMENT

The goal of this policy is to consolidate and centralize all clinical research drug and biologic management operations for all CU Anschutz research programs.

A university-managed research pharmacy established in October 2021 to augment the

services provided by licensed affiliate pharmacies such as the UCHealth Investigational Drug Service (IDS), Investigational Drug and Specialty Pharmacy Section of the Rocky Mountain Regional VA Medical Center, Children's Hospital of Colorado's Research Pharmacy and Hemophilia and Thrombosis Center Pharmacy.

All investigational products required by the protocol including premeds, topical lidocaine, oral glucose unless excluded by this policy, must be managed by a hospital pharmacy or utilize the services of the CU Anschutz Research Pharmacy.

This policy does not apply to the following products:

- Products categorized as medical devices
- Products classified as blood products
- Investigational products manufactured at CU Anschutz (e.g. Gates Biomanufacturing Facility)
- Schedule 1 drugs
- Exemptions as determined by the CU Anschutz Lead Research Pharmacist

Products not covered by this policy may require additional reviews and approvals in accordance with other campus policies and procedures.

C. ROLES AND RESPONSIBILITIES

CU Anschutz Research Pharmacy is managed by CU Anschutz Skaggs School of Pharmacy and Pharmaceutical Sciences in collaboration with the Associate Vice Chancellor for Regulatory Compliance.

Listed below are the responsibilities and capabilities of each party:

Principal Investigator and Research Teams are responsible to:

- Consult with the research pharmacy to establish a pharmacy plan and pricing
- Ensure that appropriate pricing is added to any grant or industry budget. Research funded internally is subject to this policy and must have sufficient funding to cover pharmacy costs before the study begins recruitment.
- Adhere to the process outlined in the Appendix of this document for ordering and administration of the study product.

CU Anschutz Lead Research Pharmacist is responsible for:

- Consult with the research team to develop and finalize a pharmacy plan and fee structure
- Receiving, assessing and documenting any damage to study products
- Confirming identity and strength of the received product
- Completing product shipping documents as required
- Quarantining study products if necessary (e.g. out of temperature range, damaged, expired)

- Store as required per manufacturer instructions
- Tracking receipt and dispensing of study product in the study-specific system (e.g. IWRS)
- Patient-specific single dose packaging, if required by the study
- Patient-specific unit dose dispensing, if required by the study
- Reconstitution under sterile conditions
- Placing additional labeling on products according local requirements
- Tracking and storing products returned by study subjects when applicable
- Compounding active and placebo products, or managing the outsourcing thereof, as permitted under state law
- Completing drug accountability logs from receipt to return and/or disposal of the study product(s)
- Dispensing to study team per order from a Licensed Independent Provider
- If the Research Pharmacy is unable to provide the research services required, they will be responsible for coordinating any external third party services needed.

CU Anschutz Research Pharmacy Governance Committee is the campus governing body charged by the VC for Research with responsibility for the following:

- Oversee pricing fee schedule
- Ensure appropriate resources to meet agreed upon timelines
- Oversee compliance with this policy
- Review audit reports by external and internal monitors

D. PROCESS

I. Ordering:

- a. For research visits that occur in inpatient or outpatient settings at the Affiliate Hospitals, including the Inpatient CTRC (pediatric and/or adult), the study team must follow the applicable Hospital policies and guidelines. CTRC staff must follow the applicable Hospital policies regarding investigational product ordering.
- b. For research visits that occur at the Outpatient CTRC or any University research space on campus by a physician who is a study team member and the product dispensed by or through a licensed pharmacist to a study team member.

II. Administration:

- a. For research visits that occur at the Affiliate Hospitals, including the Inpatient CTRC (pediatric and/or adult), the study team must follow the applicable Hospital policies and guidelines. CTRC staff must follow the applicable Hospital policies regarding product dispensing and administration.

- b. For research visits that occur at the Outpatient CTRC, CU Medicine clinics, or other university designated research space on campus researchers must follow the procedures as outlined below.
 - The CTRC nurses listed on the Delegation of Authority Log are allowed to administer study product in accordance with their license to the study subjects.
 - CTRC nurses, and study team members trained and listed on the delegation of duties log are allowed to distribute the study product to the study subjects for self-administration off-campus.
 - Administration of the study product by other than CTRC nurses is limited to individuals with clinical training and active licensure by the State of Colorado. Appropriate licensure includes, but is not limited to MD, DO, DDS, NP, PA, PharmD and RN.
 - The PI or other licensed medical professional delegated on the protocol must be reasonably available during administration of the study product.
 - Distribution / administration of the product must be documented in the Electronic Medical Record.

III. Distribution:

Distribution of study drug to a study subject for self-administration off-campus can be done by a study PA, NP, RN or unlicensed study coordinator, if delegated and if initiated by an order via a research note from a physician or NP in the EHR. system.

Notes

1. Dates of official enactment and amendments:

June 15, 2028: adopted and approved by the Vice Chancellor of Research

2. History:

July 1, 2021: New Policy

3. Initial Policy Effective Date: July 1, 2021.

4. Cross References/Appendix:

- United States Pharmacopeial standards (USP) chapters <795>, <797> and <800> regulations.
- Per CO law, the PA and supervising physician must adhere to the rules and regulations for licensure or and practice by physician assistants as set forth in CO Rule 400 (3 CCR 713-7)
<https://www.sos.state.co.us/CCR/Upload/AGORrequest/AdoptedRules02014-00305.PDF>