

LOUIS STOKES CLEVELAND VA MEDICAL CENTER
Medical Research Service
Subcommittee on Research Safety Policy

Effective Date: JUNE 14, 2023

SOP Title: ORDERING OF SELECT AGENTS OR HAZARDOUS CHEMICALS

SOP Number: SRS--021

SOP Version: .06

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1. **PURPOSE:** To ensure proper procurement of select agents and/or hazardous chemicals for the Medical Research Service.
2. **POLICY:** All purchase orders for select agents and/or hazardous chemicals will be reviewed by the Purchasing Clerk/Research and the Research Safety Coordinator/Chemical Hygiene Officer (RSC/CHO) prior to placing the order.
3. **DEFINITIONS:**
 - a. **Select Agent** – A select agent is one of a group of agents (viruses, bacteria, rickettsiae, fungi, toxins, and recombinant deoxyribonucleic acid (DNA)) designated by the CDC and the USA Patriot Act.
 - b. **MAXCOM** – A chemical hygiene software package that houses the entire Medical Center’s chemical inventory/Safety Data Sheets/Secondary Container Labels.
4. **PROCEDURE:**
 - a. When the Purchasing Clerk/Research or his/her designee receives a purchase order for a Select Agent and/or Hazardous Chemical, he/she will ensure that all information on the purchase order has been filled out completely by the investigator/designated laboratory personnel. This includes:
 - (1) Citation of order involving Chemical/Drug.
 - (2) Dry Ice/Refrigerator storage requirements.
 - (3) Unstable/Hazardous indication.
 - (4) Vendor (name, address, phone number).
 - (5) Catalog No.
 - (6) Common name of Select Agent or Hazardous Chemical being ordered.
 - (7) Quantity.
 - b. If not filled out completely, purchase will not be made until all information has been provided.
 - c. When purchase order satisfies the above requirements, the Purchasing Clerk/designee will present the purchase order for Select Agents or Hazardous Chemicals to the RSC/CHO for signature.
 - d. The RSC/CHO will ensure that the purchase order for Select Agents or Hazardous Chemicals is consistent with the Principal Investigator’s Research Protocol Safety Survey (RPSS). To document this process, the RSC/CHO will place his/her signature on the purchase order.

e. If a chemical to be purchased does not appear on an RPSS, the RSC must submit a request in MAXCOM and through the Facility Safety Office. When approved, an addendum to the Principal Investigator's RPSS must be submitted to the Subcommittee on Research Safety. When an addendum to add a new chemical has been approved, the new chemical can then be purchased.

f. Purchase orders for Select Agents or Hazardous Chemicals *cannot* be filled without the signature of the RSC/CHO.

g. With the help of the Purchasing Clerk/designee, the RSC/CHO will document/record purchases of Select Agents/Hazardous Chemicals and their proper delivery to laboratory personnel.

NOTE – PURCHASE OF SELECT AGENTS LIMITED TO ON-SITE LABS ONLY: VHA Program Guide 1200.16 (August 2, 2018), Paragraph 5.a.: “Use of Select Agents and Toxins (defined by the CDC list of select agents and toxins, APHIS biological agents, and the products of such) is restricted to VA owned or leased space. In the event that the VAMC leases an entire BSL-3 facility, and no affiliate research is conducted therein, an off-site waiver and MOU shall not be required; however, the lease agreement must include VA expectations for physical security to be provided by the lessee. If the VAMC leases a portion of an affiliate BSL-3 laboratory, such that affiliate research is co-mingled with VA research, an MOU for shared oversight must be implemented; however, an off-site waiver is not required.”

The VA does not have purchased or leased space at CWRU.

5. REFERENCE: VHA Handbook 1200.06 Control of Hazardous Agents in VA Research Laboratories, 42 CFR Part 73, “Possession, Use and Transfer of Select Agents and Toxins; Interim Final Rule,” US Patriot Act, 2001.

6. RESCISSION: The rescission date of this policy is June 13, 2028.

7. FOLLOW-UP: RSC/CHO