



EMORY POLICY 7.25-PURCHASE PROCESS EXCEPTION REQUEST

Emory University [Policy 7.25](#) require researchers to order and purchase Controlled Substances and Dangerous Drugs through the Emory Procurement Support Center for use in non-human subjects' research.

If the study team cannot provide Emory Procurement with the specific ordering requirements for a drug used in a research protocol, the Principal Investigator (PI) may submit an exception to Policy 7.25, which must be approved in advance.

To submit a request, the Emory PI should complete this Policy Exception Request form and send it to the Office of Research Integrity and Compliance (ORIC) at oric@emory.edu. Exception requests will be reviewed on a case-by-case basis. The approval will not set precedence for an investigator or future research.

Request for Exception

PI and Study Information

- PI name:
- Contact information (email/phone)
- Study title:
- Study IACUC # or N/A:

Drug Information

- Drug Name:
 - Controlled Substance Dangerous Drug/ Prescription Drug
- Location at which study drug(s) will be stored, prepared, and dispensed:
- Reason/justification for exception request:
 - Drug supplier requirement
 - Other. If other, explain:



Please explain the specifics supporting the exception request:

How the drug will be obtained, stored, and documentation processes

- Individuals with valid registration with the Georgia Board of Pharmacy who will purchase the drug:

- Researcher DEA # (if applicable):
- Individual who will track and document receipt of this drug:

- The location where the drug will be stored in a locked cabinet:

- The individual who will manage and record the disposition of this drug:

Please note that exception requests, when granted, are conditional upon the following:

- Proper documentation and drug storage requirements are met
- Agreement of investigator to undergo an audit by ORIC
- Implementation of corrective action if any deficiencies are noted upon audit.
- Withdrawal of the exception may occur if serious deficiencies are noted.

PI Name:

Signature:

Date:



RCRA: Internal Use Only

Request received on

Plan for purchase oversight review

Appropriate oversight of the purchase confirmed with the Procurement Office

Name of Procurement Office Representative:

Signature of Procurement Office Representative

Date:

Drug storage and documentation review

Proper drug storage and documentation requirements are met.

Name of ORIC Representative:

Signature of ORIC Representative

Date:

Request decision

Granted

Not granted

Name of Approver:

Signature of approver:

Date: