

CUMC Research Pharmacy Information Sheet

For Site Qualification and Site Initiation Visits

Contact information:

- WEBSITE: www.researchpharmacy.org
- EMAIL: researchpharmacy@columbia.edu
- TELEPHONE: (201) 568-6315

Licensed Research Pharmacy Locations:

CUMC Research Pharmacy – IP-749
161 Fort Washington Ave., IP-749
New York, NY 10032
TEL: (212) 305-8684
FAX: (212) 305-0397

CUMC Research Pharmacy – BB Satellite
William Black Building
650 W 168th St., Basement B-30
New York, NY 10032
TEL: (212) 305-9867
FAX: (212) 305-0068

CUMC Research Pharmacy – NJ
17 Smith Street
Englewood, NJ 07631
TEL: (201) 568-6315
FAX: (201) 568-6148

Hours of Operation:

Monday through Fridays from 8AM to 4PM, with on-call services during weekends and holidays.

Security:

All Research Pharmacy locations storing investigational agents are locked and secure, with access limited to Research Pharmacy personnel only, via key and security keypad or ID card sensor. All study related documents are also stored and maintained within these secured Research Pharmacy locations.

Research Pharmacist Staff:

One primary Research Pharmacist (a.k.a. the *Pharmacist on Record*, PoR) and *at least* one Back-up Pharmacist will be assigned to each clinical study supported by the Research Pharmacy.

Dispensation of Investigational Agents:

Research Pharmacy prepares and dispenses investigational agents for both the inpatient and outpatient setting.

Shipments:

The Research Pharmacy will dispense and ship investigational agents nationally and internationally, as required for a particular study or clinical trial.

Storage of Investigational Agents & Temperature Monitoring:

All Research Pharmacy locations, its Storage Rooms, and Storage Units (i.e., refrigerators and freezers) have 24/7 continuous temperature monitoring. During off-hours, the On-Call Pharmacist will be alerted via pager if temperatures deviate out of target ranges. Daily temperature recordings are available as hardcopies.

Refrigerator & Freezer Units:

Refrigerators are maintained between target ranges 2 °C to 8 °C. The Research Pharmacy is also equipped with freezers that are maintained at target ranges between -20 °C to -10 °C; -40 °C to -30 °C; and < 70 °C for investigational agents requiring storage within these temperatures.

Emergency Back-Up:

The Research Pharmacy locations are in buildings with back-up generators (NY locations) or have standard operating procedures in place (NJ Site) in the event there is a power outage. During off-hours, the On-Call Pharmacist will be alerted via pager if temperatures go out of range.

Accountability:

The Research Pharmacy captures all transactions of each study's investigational agent(s) using its electronic *Individual Drug Accountability (IDA) Log*. Handwritten logs may be maintained, if also required.

Destruction:

The Research Pharmacy performs destruction of investigational agents according to the department's *Standard Operating Procedures (SOP)*. Unless otherwise indicated, investigational agents to be destroyed are placed within the biohazard container and then incinerated per institutional policy. A copy of our *Destruction Policy* is available upon request.