Description
Specify details including investigational drug name, dosage form, strength, package size and the manufacturer. In addition, describe a placebo product (if any).

Procurement
- Specify the ordering process including:
  - Supplier
  - Staff responsible for ordering drug(s)
  - Drug ordering method and form
  - Any other specific requirements (e.g., Time restraint, subject-specific supply, automatic supply)

- Describe the drug receipt procedures including:
  - Shipping documents to file
  - The receipt confirmation with the sponsor (e.g., sponsor-provided form, web-based system)
  - Disposition of temperature recording device from the package and its record during transit (if any)

Accountability
- Specify:
  - Drug accountability record form (DARF)
  - Subject-specific drug accountability form (if any)
  - Contents in the DARF
  - Frequency of verifying accountability record against actual inventory

Storage
- Specify:
  - Storage requirements including security and acceptable temperature ranges
  - Temperature monitoring method and frequency
  - Procedures in the event of temperature excursions

Treatment Schedule
- Describe:
  - Treatment arms and assigned doses including dose calculation (if any)
  - Dose schedules (e.g., loading, maintenance and tapering doses)
  - Criteria for any dose modifications (i.e., dose escalation and/or reduction)

Dose Preparation
- If an investigational drug(s) is dispensed from a pharmacy department, specify procedures and any required documentation.
  - Time frame for a drug request (e.g., 3 to 5 days prior to the actual treatment date, 2 hours prior to the scheduled treatment time)
  - Documentation to provide the Department of Pharmacy
    - A copy of the signed informed consent form (for the first dispensation)
    - Treatment arm, dose and/or drug assignments (kit, bottle or vial numbers)
    - Drug order and/or prescriptions
    - Protocol-specific drug request forms (if any)
GUIDANCE FOR MOP: THE MANAGEMENT OF INVESTIGATIONAL DRUGS

Provide specific instructions for drug preparation.

- Randomization process
- Study-specific forms (e.g., dose calculation sheet, subject-specific dispensation records, original drug label sheet)
- Compounding instructions (e.g., reconstitution, diluents, final concentration or volume, specific requirements for IV bag, bottle and administration set, stability of both reconstituted and final product, light sensitivity, filtration, blinding method, vehicle for oral liquid forms, ancillary supplies, compounding log)
- Kit preparation
- Packaging requirements (e.g., child-proof, light protection)
- Policy on bottle opening
- Dispensing quantity and unit
- Expiration date and/or time
- Instruction to dispense the drug by mail including any pertinent forms
- Instruction to distribute the drug to other sites including any pertinent forms

Labeling: Show an example of dispensing label or describe the contents on the label.

The label shall bear:

- "Caution: New drug-limited by federal law (or US) to investigational use"
- Study identifier (e.g., IRB number)
- Prescription or drug order number (if available)
- Subject name
- Subject address or location in facility
- Subject study identification number
- Investigational drug name (or placebo)
- Investigational drug dosage form and strength
- Dispensing quantity
- Administration instructions including dose
- Directions for storage and other relevant information (e.g., Controlled substances, refrigeration, drug and/or food interactions)
- Preparation or dispensing date and/or time
- Expiration date and time
- Name of prescribing investigator
- Name of preparing/dispensing pharmacist or health professional
- Dispensing location name, address and phone number

Pick-up or Delivery

Describe your procedure to pick-up or deliver the final product (e.g., Pick-up from pharmacy by study coordinators, delivery to inpatient locations, dispensation by mail).

Administration

Provide directions for administration and any special instructions (e.g., Drug-drug or drug-food interaction, do not chew, specific instructions for IV administration).

Drug Retrieval

Describe the procedure to retrieve unused drugs and empty containers from subjects including subject compliance verification, delegated staff and disposition of the returned drug. It is recommended that you use a form for records.
Drug Disposal

Describe the procedures to return used, unused and expired drug(s) to the sponsor or to dispose of them on site. It is recommended to use a form for records.

Forms

- The following forms may be created if needed for the study.
  - Drug order form
  - Drug receipt verification form
  - Drug request form (to Pharmacy)*
  - Drug accountability record form*
  - Subject-specific dispensation form*
  - Compounding log*
  - Dose calculation form
  - Drug pick-up or delivery record form*
  - Subject drug accountability record (for subject medication compliance)*
  - Drug dispensation by mail form*
  - Drug distribution or transfer form*
  - Drug return to pharmacy form*
  - Drug return to sponsor form*
  - Drug disposal form*
  - Temperature log*
  - Temperature excursion report form*
  - Monitoring log*

*Templates for these forms are available on the HRPP website.