

COLUMBIA UNIVERSITY
POLICY FOR THE ACQUISITION, USE AND DISPOSAL
OF CONTROLLED SUBSTANCES IN RESEARCH

General Information Regarding Recordkeeping

Please refer to the sample templates for receipt, use and biennial inventories. Inventories and records of controlled substances listed in Schedule I and II shall be maintained separately from all of the records of the registrant per 21 CFR 1304.04(f)(1). All records must be maintained for a period of at least 5 years from the date of the last recorded purchase, transfer, use and other transaction per NYS Title Section 80.112(b).

Receipt Log:

- A separate receipt log is required for Schedule I – II materials and Schedule III-V.
- The PI/Licensed individual must develop their own internal container ID inventory numbering system and assign numbers to each container (ex. J. Smith - 001).
- File a copy of the purchase receipt with the receipt log and mark the date of receipt on the invoice.
- All record entries must be in English and legible. No abbreviations are permitted except for standard metric units.

Use log:

- A separate and current record for the use of each controlled substance
- One use log must be completed per container received. The PI/Licensed individual must develop their own internal container ID inventory numbering system and assign numbers to each container (ex. J. Smith - 001).
- Each record of use must be signed by the person working with the controlled substance.
- Records must be legible and written in English.
- The use of codes, symbols, abbreviations or foreign languages in identifying a controlled substance in the record is prohibited.
- Records should be kept in such a manner as to facilitate quick and accurate assessment of quantity on hand and the history of use to the individual container level or fullness amount.
- These records must be kept separately from all other records and documents, in or near the primary work area, and be readily available for inspection during regular work hours or at any other reasonable time.

Biennial Inventory:

- For biennial inventories, every 2 years from the date of the initial receipt of the CS into inventory, researchers must prepare an inventory of all controlled substances using Biennial Inventory log. The inventory can be taken either as of the opening of business or the close of business on the inventory date per 21 CFR 1304.11(a).
- The inventory must be readily available for inspection during normal business hours for at least **5 years** from the date of the last recorded purchase, transfer, use, or other transaction involving the controlled substance per NYS Title Section 80.112(b).
- A separate entry shall be made with respect to each kind of substance or preparation, and each kind or size of package. Each entry shall show:
 - the name, quantity and content of the controlled substance
 - the size of the individual package
 - the number of packages
 - the total content of all packages covered by the entry on hand as of the date of the inventory.
- If the controlled substance is listed on Schedule I or II, an exact count or measure of the contents is required per 21 CFR 1304.11(e)(3)(I). If the material is listed on Schedule III-V, an estimated count or measure of the contents may be made unless the container holds more than 1000 tablets or capsules in which case the researcher must make an exact count of the contents.
- Records must be legible and written in English. No abbreviations are permitted except for standard metric units.
- Inventories shall be maintained at the registered location per 21 CFR 1304.11(a). Inventories of controlled substances shall be deemed to be “on hand” if they are in the possession of the registrant. In the event controlled substances are stored at a location for which s the registrant is not registered, the controlled substances shall be included in the inventory for the registered location to which they are subject to control per 21 CFR 1304.11(a).
- It is recommended that the person conducting the inventory date and sign the record.
- The inventory should also include a detailed list of any controlled substances lost, destroyed, or stolen (see Reporting Loss, Theft or Unauthorized Use section of the Policy).