# FORM 1 TEMPLATE

# SELF INSPECTION OF CONTROLLED SUBSTANCES

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| **Name of Registrant** |  |
| **Registered Location** |  |
| **DEA Registration Number** |  |
| **DEA Registration Expiration Date** | Click or tap to enter a date. |

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| **Item #** | **Confirm the following** | **YES** | **Comments (if not applicable mark N/A)** |
| **Personnel** | | | |
| 1 | Are all persons who have access to the room in which Controlled Substances are stored listed on a current “Access Log” [Form 2]? |  |  |
| 2 | Is access to Controlled Substances limited to personnel who are assisting in conducting research under the Registrant? |  |  |
| 3 | Is access to Controlled Substances limited to personnel who have ***not***had a United States Drug Enforcement Agency (DEA) registration or practitioner license revoked, and do ***not***have a prior criminal history of violations related to Dangerous Drugs or Controlled Substances? |  |  |
| 4 | Have all personnel who have access to Controlled Substances signed an “UTSA University Employee and Agent Screening Statement” [Form 3]? |  |  |
| 5 | Are all persons who have access to Controlled Substances listed on a current “Controlled Substances Authorized User Signature Log” [Form 4]? |  |  |
| 6 | Is access to Controlled Substances limited to the minimum number of personnel required to conduct research using the Controlled Substances? |  |  |
| 7 | Have all personnel who have access to Controlled Substances viewed the Office of Compliance “Use of Controlled Substances in Research” training. |  |  |
| **Security** | | | |
| 1 | Are all Controlled Substances stored in the room/facility identified on the researcher’s DEA registration? |  |  |
| 2 | Are all Controlled Substances stored separately from other chemicals? |  |  |
| 3 | Are Schedule I Controlled Substances stored in a securely locked, substantially constructed cabinet or safe that is secured by a key or combination lock and is securely fastened to the floor or wall so that it cannot be easily removed? |  |  |
| 4 | Are Schedule II-V Controlled Substances stored in a substantially constructed cabinet that is secured by a key or combination lock? |  |  |
| 5 | Are cabinets/safes storing Controlled Substances of a size and weight that makes transport or concealment difficult? |  |  |
| 6 | Are cabinets/safes storing Controlled Substances constructed in a manner so that forced entry is easily detected? |  |  |
| 7 | Are carfentanil, etorphine hydrochloride and/or diprenorphine kept in a safe or steel cabinet that meets GSA Class V security container requirements (i.e., can withstand surreptitious entry, forced entry, lock manipulation and radiological attack?) |  |  |
| 8 | Is the room/facility in which Controlled Substances are stored an area where unauthorized access is easily noticed? |  |  |
| 9 | Is the room/facility in which Controlled Substances are stored locked when not in use? |  |  |
| 10 | Are lock combinations and keys to the room in which Controlled Substances are stored limited to personnel authorized to have access to the room? |  |  |
| 11 | Are lock combination and keys to the safe/cabinet in which Controlled Substances are stored limited to personnel authorized to access Controlled Substances? |  |  |
| 12 | Are all relevant lock combinations changed and keys returned upon termination of an authorized personnel’s engagement in the Registrant’s facility? |  |  |
| **Records and Labeling** | | | |
| 1 | Is the DEA Registration Certificate Form and any other documentation received in your files? |  |  |
| 2 | Has an initial inventory of all Controlled Substances been performed and recorded [Form 6]? |  |  |
| 3 | Have subsequent inventories of Controlled Substances been performed and recorded every 24 months thereafter [Form 6]? |  |  |
| 4 | Is all original documentation of orders and receipts for Controlled Substances maintained on file (including copies of DEA Form 222 for orders of Schedule I and II Controlled Substances)? |  |  |
| 5 | Are all orders and receipts of Controlled Substances logged, including PO and DEA Form 222 number, supplier name, dates, amounts, and any discrepancies between drug ordered and drug received [Forms 8 and 9]? |  |  |
| 6 | Has the third page (purchaser’s copy) of DEA Form 222 been annotated to show quantity of controlled substances received and date of receipt? |  |  |
| 7 | If Schedule I or II Controlled Substances are ordered by a person other than the Registrant, has an appropriate “DEA Power of Attorney” form been executed [Form 10]? |  |  |
| 8 | For each primary container of Controlled Substances, is usage tracked on a log, including beginning amounts, dates used, personnel who used the drug, and balance after each use (including documenting disposal) [Form 7]? |  |  |
| 9 | Are all primary bottles of Controlled Substances kept in their original container with appropriate labelling, including expiration date? |  |  |
| 10 | Are all secondary bottles (dilutions from a primary bottle) of Controlled Substances kept in containers labelled with the drug name, drug concentration, expiration date (copied from the original vial), initials of the person who transferred the drug, and unique container identification [Form 11]? |  |  |
| 11 | Are all expired Controlled Substances so labelled and separated from unexpired Controlled Substances? |  |  |
| 12 | Have arrangements been made for disposal of any expired, unusable or unwanted Controlled Substances through engagement with a licensed reverse distributor? |  |  |
| 13 | Are any significant discrepancies, including suspect theft, of Controlled Substances documented on the “Controlled Substances Discrepancy Report Form” and reported in accordance with instructions contained on that form [Form 5]? |  |  |
| 14 | Are all Controlled Substances records kept secure and separated from other business records? |  |  |
| 15 | Are Schedule I and II Controlled Substances records, including all DEA Form 222, kept separated from records pertaining to Schedule III-V Controlled Substances? |  |  |
| 16 | Are all Controlled Substances records maintained for 3 years from the final disposition of the drug? |  |  |

**Completed by:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Registrant signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_