Registrant Name: Click or tap here to enter text.

Registered Location: Click or tap here to enter text.

GBP permit # and expiration date: Click or tap here to enter text.

DEA registration # and expiration date: Click or tap here to enter text.

*Find the forms detailed in this document at* [*https://rcra.emory.edu/oric/controlled-substances/forms.html*](https://rcra.emory.edu/oric/controlled-substances/forms.html)

|  |  |  |  |
| --- | --- | --- | --- |
| **Item #** | **Confirm the following** | **YES**  | **Citations** |
| **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](https://rcra.emory.edu/_includes/documents/sections/oric/form2_al.xlsx)]? |  | [§ 21 CFR 1301.71](https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2)(b)(8) Security requirements generally. |
| 2 | Is access to Controlled Substances limited to personnel who are assisting in conducting research under the Registrant? |  | [§ 21 CFR 1301.71](https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2) (b)(11) Security requirements generally. |
| 3 | Is access to Controlled Substances limited to personnel who have ***not***had a DEA, GBP, or practitioner license or registration revoked, and do ***not***have a prior criminal history of violations related to Dangerous Drugs or Controlled Substances? |  | [§ 21 CFR 1301.76](https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2/section-1301.76)(a) Other security controls for practitioners. |
| 4 | Have all personnel who have access to Controlled Substances signed an “Emory University Employee and Agent Screening Statement” [[Form 3](https://rcra.emory.edu/_includes/documents/sections/oric/form3_eueass.docx)]? |  | § 21 CFR [1301.76](https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2/section-1301.76) Other security controls for practitioners. |
| 5 | Are all persons who have access to Controlled Substances listed on a current “Controlled Substances Authorized User Signature Log” [[Form 4](https://rcra.emory.edu/_includes/documents/sections/oric/form4_csausl.xlsx)]? |  | [§ 21 CFR 1301.71](https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2) (b)(11) Security requirements generally. |
| 6 | Is access to Controlled Substances limited to the minimum number of personnel required to conduct research using the Controlled Substances? |  | [§ 21 CFR 1301.71](https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2) (b)(11) Security requirements generally. |
| 7 | Have all personnel who have access to Controlled Substances viewed the Office of Research Integrity and Compliance (ORIC) “Use of Controlled Substances in Research” training materials [found at [*https://rcra.emory.edu/oric/controlled-substances/training.html*](https://rcra.emory.edu/oric/controlled-substances/training.html)*)*]?  |  | Best Practice |
| **Security** |
| 1 | Are all Controlled Substances stored in the room/facility identified on the Registrant’s GBP permit and DEA registration? |  | [§ 21 CFR 1301.11](https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFR0f5a129834f0129/section-1301.11)(a) |
| 2 | Are all Controlled Substances stored separately from other chemicals?  |  | [§ 21 CFR 1301.71](https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2) Security requirements generally & § 21 CFR [1301.72](https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2#1301.72)(b)(8)(ii |
| 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? |  | § 21 CFR [1301.75](https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2/section-1301.75)(a) |
| 4 | Are Schedule II-V Controlled Substances stored in a substantially constructed cabinet that is secured by a key or combination lock? |  | § 21 CFR [1301.75](https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2/section-1301.75)(b) |
| 5 | Are cabinets/safes storing Controlled Substances of a size and weight that makes transport or concealment difficult? |  | § 21 CFR [1301.72](https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2/section-1301.72) |
| 6 | Are cabinets/safes storing Controlled Substances constructed in a manner so that forced entry is easily detected? |  | § 21 CFR [1301.72](https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2/section-1301.72) |
| 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?) |  | 21 CFR [1301.75](https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2/section-1301.75)(e) |
| 8 | Is the room/facility in which Controlled Substances are stored an area where unauthorized access is easily noticed? |  | 21 CFR [§ 1301.71](https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2) (b)(10) Security requirements generally. |
| 9 | Is the room/facility in which Controlled Substances are stored locked when not in use? |  | 21 CFR [§ 1301.71](https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2) (b)(9) Security requirements generally. |
| 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? |  | 21 CFR [§ 1301.71](https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2) (b)(8) Security requirements generally. |
| 11 | Are lock combination and keys to the safe/cabinet in which Controlled Substances are stored limited to personnel authorized to access Controlled Substances? |  | 21 CFR [§ 1301.71](https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2) (b)(8) Security requirements generally. |
| 12 | Are all relevant lock combinations changed and keys returned upon termination of an authorized personnel’s engagement in the Registrant’s facility? |  | 21 CFR [§ 1301.71](https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2) (b)(8) Security requirements generally. |
| **All the above is used by DEA to determine if the Registrant has adequate control over the controlled substances. 21 USC 823 (g) Failure to maintain control could result in the loss of license.**  |
| **Records and Labeling** |
| 1 | Is the GDNA Researcher Permit Inspection Form and any other documentation received in your files? |  | [21 U.S. Code § 205](https://www.bing.com/ck/a?!&&p=b23d7aa79cf20f98JmltdHM9MTY4MDEzNDQwMCZpZ3VpZD0yMTg1ODkwNS00ZmEwLTZlZTAtMzM4Ni05OGU5NGJhMDYwNzUmaW5zaWQ9NTQxNQ&ptn=3&hsh=3&fclid=21858905-4fa0-6ee0-3386-98e94ba06075&psq=requirement+to+display+pharmacy+license&u=a1aHR0cHM6Ly93d3cubGF3LmNvcm5lbGwuZWR1L3VzY29kZS90ZXh0LzIxLzIwNSM6fjp0ZXh0PUV2ZXJ5JTIwbGljZW5zZSUyMHRvJTIwcHJhY3RpY2UlMjBwaGFybWFjeSUyMHNoYWxsJTIwYmUlMjBjb25zcGljdW91c2x5LDMlMkMlMjAxOTE1JTJDJTIwY2guJTIwNzQlMkMlMjAlQzIlQTclRTIlODAlQUY1JTJDJTIwMzglMjBTdGF0LiUyMDgxOS4lMjk&ntb=1) GBP only |
| 2 | Is the Drug Enforcement Agency (DEA) Registration Certificate Form and any other documentation received in your files? |  | 21 CFR [1301.35](https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFR3b1489fb21ea6df/section-1301.35)(c) |
| 3 | Has an initial inventory of all Controlled Substances been performed and recorded [[Form 6](https://rcra.emory.edu/_includes/documents/sections/oric/form6_csi.xlsx)]? |  | 21 U.S.C. 827(a)(1); 21 CFR [1304.11](https://www.ecfr.gov/current/title-21/chapter-II/part-1304/subject-group-ECFR9944e94ba5f1eb0/section-1304.11)(b) |
| 4 | Have subsequent inventories of Controlled Substances been performed and recorded every 24 months thereafter [[Form 6](https://rcra.emory.edu/_includes/documents/sections/oric/form6_csi.xlsx)]? |  | 21 CFR [1304.11](https://www.ecfr.gov/current/title-21/chapter-II/part-1304/subject-group-ECFR9944e94ba5f1eb0/section-1304.11)(c) |
| 5 | 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)? |  | 21 CFR. [1305.17](https://www.ecfr.gov/current/title-21/chapter-II/part-1305)(a) |
| 6 | Are all orders and receipts of Controlled Substances logged, including PO/invoice and DEA Form 222 number, supplier name, dates, amounts, and any discrepancies between drug ordered and drug received [[Forms 8](https://rcra.emory.edu/_includes/documents/sections/oric/form8_orlcssi-ii.xlsx) and [Form 9](https://rcra.emory.edu/_includes/documents/sections/oric/form9_orlcssiii-v.xlsx)]? |  | 21 CFR. [1305.17](https://www.ecfr.gov/current/title-21/chapter-II/part-1305)(a)[1304](https://www.ecfr.gov/current/title-21/chapter-II/part-1304).22(a), (d) |
| 7 | Has the purchaser’s copy of DEA Form 222 been annotated to show quantity of controlled substances received and date of receipt? |  | 21 CFR. [1305.13](https://www.ecfr.gov/current/title-21/chapter-II/part-1305/subpart-B/section-1305.13) (e) |
| 8 | Did you have any defective DEA Form 222? If so, do you have the reason to return stapled to the defective DEA Form 222? |  | 21 CFR. [1305.17](https://www.ecfr.gov/current/title-21/chapter-II/part-1305)(c) |
| 9 | 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](https://rcra.emory.edu/_includes/documents/sections/oric/form10_deapa.pdf)]? |  | 21 CFR [1305.05](https://www.ecfr.gov/current/title-21/chapter-II/part-1305/subpart-A/section-1305.05)(a) |
| 10 | 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](https://rcra.emory.edu/_includes/documents/sections/oric/form7_cscudl.xlsx)]? |  | 21 CFR [1304](https://www.ecfr.gov/current/title-21/chapter-II/part-1305/subpart-A/section-1305.04).22(c) |
| 11 | Are all primary bottles of Controlled Substances kept in their original container with appropriate labelling, including expiration date? |  | § [16-13-75](https://gbp.georgia.gov/document/laws-policies-rules/title-16-chapter-13-crimes-and-offenses-controlled-substances-updated/download) - Drugs to be kept in original container |
| 12 | Are all secondary bottles (dilutions from a primary bottle) of Controlled Substances kept in containers labelled with the drug name, schedule, drug concentration, expiration date (copied from the original vial), initials of the person who transferred the drug, and unique container identification [[Form 11](https://rcra.emory.edu/_includes/documents/sections/oric/form11_csdul.docx)]? |  | §21 CFR [1302](https://www.ecfr.gov/current/title-21/chapter-II/part-1302) LABELING AND PACKAGING REQUIREMENTS FOR CONTROLLED SUBSTANCES |
| 13 | Do you have all the destruction records from the reverse distributor? DEA Form 222 and invoices? |  | § [1304](https://www.ecfr.gov/current/title-21/chapter-II/part-1304).21(e) General requirements for continuing records. |
| 14 | Have arrangements been made for disposal of any expired, unusable or unwanted Controlled Substances through engagement with a licensed reverse distributor? |  | 21 CFR. [1317](https://www.ecfr.gov/current/title-21/chapter-II/part-1317/subpart-A).05 |
| 15 | Where there any significant discrepancies in the inventory or logs, including suspect theft, of Controlled Substances?  |  | 21 CFR. [1301.74](https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2/section-1301.74)(c) |
| 15a | If yes, were those documented on the “Controlled Substances Discrepancy Report Form” and reported in accordance with instructions contained on that form [[Form 5](https://rcra.emory.edu/_includes/documents/sections/oric/form5_csdr-vs-3-10-22.docx)]? |  | [21 CFR 1301.76](https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2/section-1301.76)(b) |
| 16 | Do you have an SOP or checklist in your records in case of lost or theft of Controlled Substances? [Find an example here](https://rcra.emory.edu/_includes/documents/sections/oric/sop-loss-theft-cs). |  | Best practice |
| 17 | Are all Controlled Substances records kept secure and separated from other business records? |  | 21 CFR. [1304.04](https://www.ecfr.gov/current/title-21/chapter-II/part-1304)(h) |
| 18 | Are Schedule I and II Controlled Substances records, including all DEA Form 222, kept separated from records pertaining to Schedule III-V Controlled Substances? |  | 21 CFR. [1304.04](https://www.ecfr.gov/current/title-21/chapter-II/part-1304)(f)1 |
| 19 | Are all Controlled Substances records maintained for 2 years from the final disposition of the drug? |  | 21 CFR [1304.04](https://www.ecfr.gov/current/title-21/chapter-II/part-1304)(a),  |
| Every registrant is required to keep complete and accurate records (21 CFR 1304.21). This section is designed to help you maintain that regulation.  |

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

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