Registrant Name:

Registered Location:

GBP permit # and expiration date:

*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** | **Comments** |
| **Personnel** | | | |
| 1 | Is access to Dangerous Drugs limited to personnel who are assisting in conducting research under the Registrant? |  | [Rule 480-7-.04 (7)](https://casetext.com/regulation/georgia-administrative-code/department-480-rules-of-georgia-state-board-of-pharmacy/chapter-480-7-permits/rule-480-7-04-researchers-permit) |
| 2 | Is access to Dangerous Drugs 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? |  | [Rule 480-7-.04 (6)](https://casetext.com/regulation/georgia-administrative-code/department-480-rules-of-georgia-state-board-of-pharmacy/chapter-480-7-permits/rule-480-7-04-researchers-permit) |
| 3 | Is access to Dangerous Drugs limited to the minimum number of personnel required to conduct research using the Dangerous Drugs? |  | [Rule 480-7-.04 (7)](https://casetext.com/regulation/georgia-administrative-code/department-480-rules-of-georgia-state-board-of-pharmacy/chapter-480-7-permits/rule-480-7-04-researchers-permit) |
| 4 | Are all personnel who have access to Dangerous Drugs listed on a current authorized user log? [[Dangerous Drugs Form A](https://rcra.emory.edu/_includes/documents/sections/oric/forma_ddausl.xlsx)] |  | Best Practice to maintain security over drugs |
| 5 | Have all personnel who have access to Dangerous Drugs viewed the Office of Research Integrity and Compliance (ORIC) “Tutorial on Use of “Dangerous Drugs” in Research” [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 Dangerous Drugs stored in the room/facility identified on the researcher’s registration? |  | [Rule 480-7-.04 (7)](https://casetext.com/regulation/georgia-administrative-code/department-480-rules-of-georgia-state-board-of-pharmacy/chapter-480-7-permits/rule-480-7-04-researchers-permit) |
| 2 | Are all Dangerous Drugs stored in a container secured by a key or combination lock? |  | [Rule 480-7-.04 (7)](https://casetext.com/regulation/georgia-administrative-code/department-480-rules-of-georgia-state-board-of-pharmacy/chapter-480-7-permits/rule-480-7-04-researchers-permit) |
| 3 | Are all Dangerous Drugs stored in a room/facility secured by a key or combination lock? |  | [Rule 480-7-.04 (7)](https://casetext.com/regulation/georgia-administrative-code/department-480-rules-of-georgia-state-board-of-pharmacy/chapter-480-7-permits/rule-480-7-04-researchers-permit) |
| 4 | Is the room/facility in which Dangerous Drugs are stored locked when authorized personnel are not present? |  | [Rule 480-7-.04 (7)](https://casetext.com/regulation/georgia-administrative-code/department-480-rules-of-georgia-state-board-of-pharmacy/chapter-480-7-permits/rule-480-7-04-researchers-permit) |
| 5 | Are lock combinations and keys to the container in which Dangerous Drugs are stored limited to personnel who are authorized to have access to Dangerous Drugs? |  | [Rule 480-7-.04 (7)](https://casetext.com/regulation/georgia-administrative-code/department-480-rules-of-georgia-state-board-of-pharmacy/chapter-480-7-permits/rule-480-7-04-researchers-permit) |
| 6 | Are all relevant lock combinations changed and keys returned upon termination of an authorized user’s engagement in the Registrant’s facility? |  | [Rule 480-7-.04 (7)](https://casetext.com/regulation/georgia-administrative-code/department-480-rules-of-georgia-state-board-of-pharmacy/chapter-480-7-permits/rule-480-7-04-researchers-permit) |
| **Records and Labeling** | | | |
| 1 | Is the Georgia Drugs and Narcotics Agency (GDNA) Researcher Permit Inspection Form and any other documentation received in your files? |  | [Rule 480-7-.04 (8)](https://casetext.com/regulation/georgia-administrative-code/department-480-rules-of-georgia-state-board-of-pharmacy/chapter-480-7-permits/rule-480-7-04-researchers-permit) |
| 2 | Are all orders and receipts of Dangerous Drugs logged, including PO numbers, supplier name, dates, amounts, and any discrepancies between the drug ordered and drug received? [[Dangerous Drugs Form B](https://rcra.emory.edu/_includes/documents/sections/oric/formb_ddor.xlsx)] |  | [Rule 480-7-.04 (8)](https://casetext.com/regulation/georgia-administrative-code/department-480-rules-of-georgia-state-board-of-pharmacy/chapter-480-7-permits/rule-480-7-04-researchers-permit) |
| 3 | Is all backup documentation (e.g., packing list, shipment documentation, etc.) for orders placed & received retained for 2 years? |  | [Rule 480-7-.04 (8)](https://casetext.com/regulation/georgia-administrative-code/department-480-rules-of-georgia-state-board-of-pharmacy/chapter-480-7-permits/rule-480-7-04-researchers-permit) |
| 4 | For each container of Dangerous Drugs, is usage tracked on a log, including amount present, dates used, personnel who used the drug, and balance after each use (including documenting disposal)? [[Dangerous Drugs Form C](https://rcra.emory.edu/_includes/documents/sections/oric/formc_ddudl.xlsx)] |  | [Rule 480-7-.04 (8)](https://casetext.com/regulation/georgia-administrative-code/department-480-rules-of-georgia-state-board-of-pharmacy/chapter-480-7-permits/rule-480-7-04-researchers-permit) |
| 5 | Are all containers of Dangerous Drugs appropriately labeled, including expiration date? |  | [Rule 480-7-.04 (7)](https://casetext.com/regulation/georgia-administrative-code/department-480-rules-of-georgia-state-board-of-pharmacy/chapter-480-7-permits/rule-480-7-04-researchers-permit) |
| 6 | Are dangerous drugs kept separate from controlled substances unless you have expressed written consent from DEA to store non-controls with controlled substances. |  | [21 CFR 1301.72(b)(8)(ii)](https://www.ecfr.gov/current/title-21/chapter-II/part-1301) |
| 7 | Are expired drugs promptly disposed of in accordance with Emory Environmental Health and Safety Office instructions? |  | [Emory Policy 7.29](https://emory.ellucid.com/documents/view/17539/?security=a5228c342b631855d73ad419da915fadd74f3783) |
| 8 | Are all records kept for two years after the final disposition of the Dangerous Drug? |  | [Rule 480-7-.04 (8)](https://casetext.com/regulation/georgia-administrative-code/department-480-rules-of-georgia-state-board-of-pharmacy/chapter-480-7-permits/rule-480-7-04-researchers-permit) |

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

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