# GDNA/DEA Pre-Registration Inspection Checklist

The following list comprises items compiled from previous pre-registration inspections. Please be aware that every inspector is different and may ask for more or less than what is listed below. Once you have compiled the following items you may place them in your GDNA/DEA Ready Binder. Blank forms should always be printed from this website: [Forms | Emory University | Atlanta GA](https://rcra.emory.edu/oric/controlled-substances/forms.html). You are not required to use these forms, but you should use forms that document all the GDNA and DEA documentation requirements.

**Reference information**: [What is a Controlled Substance (CS)?](https://deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf) and [What is a Dangerous Drug (DD)?](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Frcra.emory.edu%2F_includes%2Fdocuments%2Fsections%2Foric%2Fdd-list.xlsx&wdOrigin=BROWSELINK)

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| --- | --- | --- | --- | --- |
| Item # | Item  | Yes | No | N/A (No CS) |
| Documentation  |
| 1 | Is the address, building name and room number where drugs **will be stored** accurate on application(s)? Be prepared to discuss where drugs will be dispensed/administered. |  |  |  |
| 2 | Copy of Full Protocol(s) easily accessible for review if needed  |  |  |  |
| 3 | Copy of Registrant CV/Resume |  |  |  |
| 4 | Brief Synopsis of Protocol(s) including but not limited to: * Type of study (in vivo, etc.)
* Type of animals used in research
* Funding source
* Purpose of Research/objective
* Describe the research process
* Purpose of drugs requested
* How much drug will you have at one time
 |  |  |  |
| 5 | Copy of Blank Receiving Form (Form 7 or 8 for CS and Form B for DD) |  |  |  |
| 6 | Copy of Blank Use (Dispensing/administration) Forms Researcher intends to use (Form 7 for CS and Forms C, D, or G, according to the DD used)  |  |  |  |
| 7 | Copy of Blank Dilution Forms (if applicable) Form 11 for CS or Form F or H for DD |  |  |  |
| 8 | Copy of Blank Destruction Form (Form 4 for CS and Form I for DD) |  |  |  |
| 9 | Copy of Blank Inventory Form for CS (Form 6) |  |  |  |
| 10 | Copy of POA for authorized purchaser (Schedule I & II CS only) |  |  |  |
| 11 | Copy of due diligence statement describing how you will prevent diversion of controlled substances: *Print, review & place in binder [SOP for the Report of Loss or Theft of Controlled Substances](https://rcra.emory.edu/_includes/documents/sections/oric/cs_due_diligence_sop.pdf)* |  |  |  |
| Personnel |
| 12 | List of Personnel who will have access to controlled drugs. (Form 2) |  |  |  |
| 13 | Who conducts background checks (Emory uses the following for employees):HireRight LLCPO Box 8478911950 N Stemmons Fwy Suite 5010Dallas TX 75284-7891 |  |  |  |

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| --- | --- | --- | --- | --- |
| Item # | Item  | Yes | No | N/A (No CS) |
| Physical Security and Background |
| 14 | Who conducts pre-employment drug tests? EHC Wesley Woods – Employee Health handles the Drug Screening and Health Assessments |  |  |  |
| 15 | Brief description of **building** where drugs are kept including:* Hours of operation
* Square footage of the building
* Is there a security system (Cameras/motion sensors)
* Access limitations to building (card access)
* Is there security (patrolled)
* Responding Agency in security event
* Describe local crime level (low in a commercial area)
 |  |  |  |
| 16 | Brief description of **room** where drugs are kept including:* Hours of operation of lab
* Square footage of the room
* Is there a security system for the lab (Cameras/motion sensors)
* Access limitations to building (card access, key access)
 |  |  |  |
| Drug Storage Area |
| 17 | Brief description of where drugs will be kept (include pictures).* Describe dimensions of cabinet/safe
* Maker of safe (if applicable)
* Type of locking system
 |  |  |  |
| 18 | Is cabinet/safe bolted to the wall or not easily moveable? |  |  |  |
| Drugs |
| 19 | List of Dangerous Drugs with intended annual amount use (see instructions for link to what are dangerous drugs) |  |  |  |
| 20 | List of CS with intended annual amount use (include drugs schedules and codes for Schedule I & II) (see instructions for link to what is a CS) |  |  |  |
| 21 | Description of how drugs are delivered and received at lab |  |  |  |
| 22 | Describe how DD are destroyed? * EHSO
 |  |  |  |
| 23 | Describe how CS are destroyed: Name, address, and DEA # of reverse distributor |  |  |  |
| 24 | Provide Name & Address of all DD Suppliers |  |  |  |
| 25 | Provide Name, Address, and DEA # of all CS Suppliers |  |  |  |