Maryland
DEPARTMENT OF HEALTH

Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Acting Secretary

Office of Provider Engagement and Regulation (OPER)
Office of Controlled Substances Administration (OCSA)
1223 West Pratt Street
Baltimore, Maryland 21223
Sandra Yankosky, Acting Deputy Director

OCSA MARYLAND RESEARCHER QUESTIONNAIRE

Applicant Name _____
Facility Name _____
Address _____
Telephone _____Fax. _____
E-mail Address _____
Maryland CDS Registration Number _____ Exp. Date_____
DEA Registration Number _____ Exp. Date_____
Hours of Operation M-F _____Sat. _____Sun. _____

1. Brief description of the applicant's background.

2. Brief description of the research that will be conducted and how controlled dangerous substances (CDS) will be used.

3. List the approximate quantities of each CDS used per year. *Include strength or concentration of the CDS and container size.*

4. Who are the individuals with access to the CDS? Include job title and/or professional title and/or educational degree for each person. *Individuals with access include all persons with access to the CDS storage area and all persons that handle the CDS.*

5. What is the exact location in your facility where CDS will be stored? *Include the location/name of the building and room number of the storage area.*

6. Provide the name, address, phone number, DEA registration number, Maryland CDS registration number and (if applicable) the Maryland Board of Pharmacy distributor or pharmacy permit for ALL suppliers of CDS. *Suppliers of prescription CDS products must have a Board of Pharmacy distribution permit or pharmacy permit. Suppliers of CDS bulk powders and chemicals do not require a Board permit. You may not purchase or receive CDS from a supplier that does not have an active Maryland CDS registration.*

7. Provide the name, address, phone number and DEA number of the reverse distributor used for disposal of outdated/unwanted CDS. (COMAR 10.19.03.10D) *Any alternate disposal procedure must be approved in writing from your local DEA office. Written permission should be kept on file at the site.*

8. What procedures are used to ensure secure delivery and receipt of CDS?

9. How will CDS be stored? *CDS must be kept either in a lockable safe or under a double lock system (a locked drawer or cabinet within a room with a lockable door). Storage area and/or safe should be kept locked when not in use and ONLY accessible to individuals approved by the registrant.*

10. Describe the method used to document receipt, usage and on-hand counts of CDS.

PLEASE READ AND INITIAL THE FOLLOWING REQUIREMENTS AND RECOMMENDATIONS

- **An initial inventory must be taken of all CDS items present prior to the opening of the business. If no CDS products are present, state "No CDS products at opening of business". [21 CFR 1304.11] (initial_____)**
- **You are required to take a biennial CDS inventory, which is a physical inventory of all controlled substances on hand that is taken at least every two years. The biennial inventory may be taken on any date, which is within two years of the previous biennial or initial inventory. [21 CFR 1304.11] (initial_____)**
- **When taking a CDS biennial inventory, schedule II items should be listed separately from the schedule III-V items. An exact count must be made of all schedule II items. Schedule III-V items may be estimate, but if fractions or decimals are used, then the container size must also be included. An exact count must be made if CIII-V products are in opened containers of greater than 1,000 tablet or capsules. All CDS, including expired and unwanted items, must be included in the inventory. The entire inventory should be taken on the same day with the same reference point (either before opening of business or after close of business). The date taken and reference point should be present on the inventory. [21 CFR 1304.11] (initial_____)**
- **Invoices for schedule III-V must be physically dated upon receipt. It is recommended that these invoices by filed separately. [21 CFR 1304.21] (initial_____)**
- **DEA 222 forms, used to order schedule I-II products, must be signed by the person who signed the most recent application for the establishment's DEA registration. A power-of-attorney may be executed by the person authorized to sign the DEA 222 form, to allow others to sign the DEA 222 form. The power-of-attorney must be kept on file at the registered site. [21 CFR 1305.05] (initial_____)**
- **When schedule I-II orders are received, the quantity and date received must be recorded for each line item on DEA Form 222. [21 CFR 1305.13(e)] (initial_____)**
- **Executed DEA 222 Forms must be maintained separately from other records and kept readily available for 2 years. [21 CFR 1305.17] (initial_____)**
- **The theft or significant loss of CDS must be reported immediately upon discovery, within one business day, in writing, to the local DEA office and the Office of Controlled Substances Administration (OCSA). A DEA Form 106 must be completed for any theft or significant unresolved loss of CDS, with the original sent to DEA and a copy sent to OCSA. The DEA 106 Form may be filed electronically to the DEA, but a copy must be printed and sent to OCSA. [COMAR 10.19.03.12B(4)] (initial_____)**

NOTE: Please ensure that all questions have been answered completely. Incomplete answers and missing information will result in a delay in the processing of your CDS application.

Signature of Applicant _____ Date _____

Print Name of Applicant _____