Controlled Substances SOP 07: DEA 222 Forms Management and Use

1. Purpose
This procedure covers the handling of DEA 222 forms used in procuring or disposing of Schedule II controlled substances at Caltech.

2. Regulatory References
21 CFR 1305

3. Training Requirements
All Controlled Substances SOP.

4. General Information
A. Abbreviations:
   1) Controlled Substance (CS)
   2) Institute Point of Contact, Director of Research Compliance (IPOC)
   3) Central Controlled Substances Custodian (CCSC)
   4) Laboratory Controlled Substances Custodian (LCSC)
   5) Principal Investigator (PI)
   6) Authorized Person (AP)
   7) Controlled Substances Tracking System (CST)
   8) Office of Laboratory Animal Resources (OLAR)
   9) Office of Research Compliance (ORC)
  10) Environmental Health and Safety (EHS)
  11) Employee and Organizational Development (EOD)
  12) Unified Distribution, Transfer, and Disposal Form (UDTD)

B. Caltech has two DEA licenses, one managed by EHS and one managed by OLAR. Each license has its own CCSC, who is responsible for implementing this SOP, as described.

5. Procedure
The DEA is transitioning from a triplicate DEA Form 222 to a single sheet form. The procedures described below delineate differences between the use of the single vs. triplicate forms. After October 30, 2021, triplicate forms will no longer be accepted.

A. Ordering of DEA 222 Forms
   1) Each CCSC must request DEA 222 forms from the IPOC. Please note the fulfillment of orders can take between 2-4 weeks.
   2) The IPOC will order DEA 222 Forms for each specific license, as requested by the CCSC, through the secured DEA website. The DEA222 Forms will be delivered directly to the requesting CCSC.
B. Receipt and Recording of DEA 222 Forms

1) Upon receipt of the DEA 222 Forms, the CCSC shall enter the DEA 222 serial numbers into the designated CCSC DEA 222 Excel file (see sample below), including the date of receipt.

The CCSC shall highlight the new entries using a reference color that indicates that these serial numbers are new and unused. For example:

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEA 222 Form #</td>
<td>Date Forms Received</td>
<td>Date Used</td>
<td>Substances Listed</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>190088041</td>
<td>11/2019</td>
<td>3/11/2019</td>
</tr>
<tr>
<td>5</td>
<td>190088043</td>
<td>11/2019</td>
<td>2/25/2019</td>
</tr>
<tr>
<td>6</td>
<td>190088044</td>
<td>11/2019</td>
<td>7/1/2019</td>
</tr>
<tr>
<td>7</td>
<td>190088045</td>
<td>11/2019</td>
<td>2/24/2019</td>
</tr>
<tr>
<td>8</td>
<td>190088046</td>
<td>11/2019</td>
<td>8/16/2019</td>
</tr>
<tr>
<td>9</td>
<td>190088047</td>
<td>11/2019</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>192868510</td>
<td>2/2019</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>192868511</td>
<td>2/2019</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>192868512</td>
<td>2/2019</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>192868513</td>
<td>2/2019</td>
<td></td>
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<tr>
<td>14</td>
<td>192868514</td>
<td>2/2019</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>192868515</td>
<td>2/2019</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>192868516</td>
<td>2/2019</td>
<td></td>
</tr>
</tbody>
</table>

2) The CCSC shall then store the DEA 222 Forms in a designated secure location, for future use.

3) If a supplier rejects the order and returns a DEA222 Form, Copies 1 and 2 of the triplicate form or the original DEA222 Form for a single form must be attached to Copy 3 or the Copy of the original DEA222 Form, and retained in accordance with our records retention requirements.

C. Preparing a DEA 222 Form for Purchase

1) When a laboratory initiates a purchase of a Schedule II CS for research use, the CCSC will prepare a DEA222 Form, and must complete an additional step in the Techmart approval process.

2) In Techmart, the CCSC will include the following note in the “Supplier's Instructions”:

“DEA 222 Form required for this material. Please contact [yourCCSCemail]@caltech.edu to secure form.”
3) The CCSC will complete the DEA 222 Form as follows:

**Sample DEA Form 222**

![Sample DEA Form 222](image)

a. Using a typewriter, computer printer, pen or indelible pencil, enter the supplier name, address, city, state, and zip in the appropriate fields.

b. Enter the date you are executing the form in the date field.

c. Enter the number of packages, size, and concentration or quantity of the CS Schedule II material in the corresponding fields. Only one item per line. You may have more than one package of the same item, though. When using triplicate forms, one form must be used exclusively for the purchase of any one of the following: carfentanil, etorphine hydrochloride, and diprenorphine. In these cases, no more than one item can be on the DEA 222 Form.

d. Enter the number of lines used in the appropriate field. In this example, only two lines were used, so a “2” was entered in the area marked.

Updated: July 30, 2020
e. The CCSC must sign the form in the signature field.

f. Copy Submission and Retention: Triplicate vs. Single Copies:

i. Triplicate Copies: All three copies must be completed as described, above. The CCSC shall retain Copy 3, pursuant to record retention requirements, and submit Copies 1 and 2 to the supplier via FEDEX overnight. At the time of submission, provide any other documentation required by the supplier (e.g. copy of license). The CCSC must retain Copy 3 for the respective license files and be able to present it for inspection by a DEA Officer if requested.

ii. Single Copy Forms: The original form must be completed as described, above. The CCSC must make a copy of the original single DEA 222 Form and submit the original to the supplier via FEDEX overnight. At the time of submission, provide any other documentation required by the supplier (e.g. copy of license). The copy of the original 222 Form may be maintained in paper or electronic form, pursuant to record retention requirements.

g. The CCSC shall update the DEA 222 Excel File, to indicate, for the appropriate serial number, the date used and the CS Schedule II substances ordered. At this time, the reference highlight color should be changed to indicate the form has been used. On the CCSC DEA 222, highlight the box from Green to Orange.

D. Receipt of DEA CS II Material

Upon receipt of the CSII Material:

1) The CCSC must record on their copy of the DEA 222 Form (whether it is Copy 3 or the copy of the single form), the number of containers (Packages Shipped) and the dates upon which those packages were received by (Date Shipped) Caltech.

2) The CCSC will generate a UDTD electronically using the CST System. In the “Notes” Section of the UDTD, enter the corresponding DEA 222 Form serial number. See Example:

![OLAR DEA 222 Forms Tracking Table]

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1 Triplicate forms will not be accepted after October 20, 2021.
3) When the UDTD forms have been printed and signed by the LCSC and the CCSC, attach a photocopy of the DEA 222 Form Copy 3/or original to the CCSC copy of the UDTD.

E. Records Retention – DEA 222 Forms

1) DEA Forms 222 must be maintained separately from all other records of the registrant. DEA Forms 222 are required to be kept available for inspection for a period of two years.

2) Any copies attached to the UDTD, must be retained along with the UDTD and are subject to the records retention requirement of the UDTD.

F. Loss of DEA 222 Forms

- If DEA 222 Forms become lost or destroyed, immediately report the incident to the IPOC along with the numbers of the DEA 222 forms that have been lost or destroyed.

G. DEA222 Forms for Reverse Distribution

- When CS Schedule II are released to a reverse distributor vendor, the vendor will issue a DEA222 form. These DEA222 Forms should be kept with the DEA Form 41 and maintained pursuant to the records retention requirements for the DEA Form 41. Upon completion of any DEA 222 forms, a copy of the DEA 222 should be send to the Registration Section of the local Los Angeles field office or emailed to DEA.Orderforms@usdoj.gov.