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, Chief Research Policy Officer (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

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 DEA 222 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 from the same batch of forms. For example:

	A	B	C	D	E
1	OLAR DEA 222 Forms Tracking				
2	DEA 222 Form #	Date Forms Received	Date Used	Substances Listed	CN #
3	192868510	2/1/2019	9/8/2020	Fentanyl Hcl, Codeine, Hydrocodone bitartrate	1234
4	192868511	2/2/2019	9/8/2020	Sufentanil citrate, tartrato de levorphanol, morphine sulfate	2345
5	192868512	2/3/2019	2/25/2021	Morphine 10mg/ml, 2ml x box of 25	3456
6	192868513	2/4/2019	2/25/2021	Fentanyl 0.05mg/ml, 2ml xbox of 25	4567
7	192868514	2/5/2019	3/23/2021	Fentanyl HCl 10mg x 5	5678
8	192868515	2/6/2019	7/8/2021	Levorphanol tartrate 500mg x 1	6789
9	192868516	2/7/2019	9/13/2021	Fentanyl 0.05mg/ml, 2ml xbox of 25	7689
10	210536362	4/15/2021			
11	210536363	4/15/2021			
12	210536364	4/15/2021			
13	210536365	4/15/2021			
14	210536366	4/15/2021			
15	210536367	4/15/2021			
16	215036368	4/15/2021			
17	215036369	4/15/2021			
18	2150363670	4/15/2021			
19	2150363671	4/15/2021			

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

3) If a supplier rejects the order and returns a DEA 222 Form, the original DEA 222 Form must be 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 must complete the standard TechMart process with one additional step

a. 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.”

2) The CCSC will print the TechMart PO page to be included in the CS order.

3) The CCSC must then prepare the DEA form 222 to complete the ordering process.

The CCSC will complete the DEA 222 Form as follows:

a. One form must be used exclusively for the purchase of any one of the following per 21CFR, Part 1305: carfentanil, etorphine hydrochloride, and diprenorphine. Please note there is a special supplier review process for these drugs. In these cases, no more than one item can be on the DEA 222 Form.

b. The CCSC completes the form according to the instructions on the back of the form.

c. Enter the last line completed in the box in the lower left corner of the form.

Copy Submission and Retention:

i. 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.

ii. At the time of submission, provide a copy of the TechMart page that includes the PO#.

iii. Include any other documentation required by the supplier (e.g. copy of license, Power-of-Attorney if not on file). If this is the first time ordering from a specific CS supplier, call the supplier prior to submitting the DEA 222 form to confirm whether any additional documentation is necessary to process the order.

iv. In the event that the DEA 222 form is rejected by the supplier, it will be returned to the CCSC. This form must be saved as part of the retention record for two years.

v. The copy of the original 222 Form should be maintained **in paper form** until the drug is ready for disposal, at which point the EHS CCSC will digitize the 222 form and UDTD and keep in disposal file. The OLAR CCSC will maintain the 222 form and UDTD in paper form, pursuant to record retention requirements.

vi. The CCSC will complete section 5 when the drug is received.

The CCSC shall update the DEA 222 Excel File to indicate the appropriate serial number, the date used, the CS Schedule II substances ordered, and the CN upon receipt of the drug and registration into the CST.

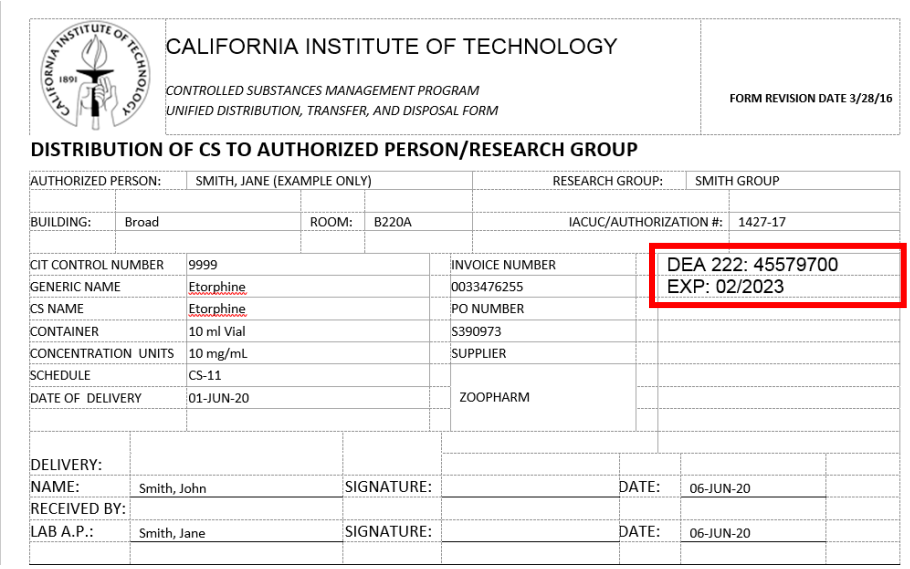
OLAR DEA 222 Forms Tracking				
DEA 222 Form #	Date Forms Received	Date Used	Substances Listed	CN #
190684041	~11/2018	3/11/2019	Sufentanil Citrate	1234
190684042	~11/2018	3/11/2019	VOIDED	n/a

D. Receipt of DEA CS II Material

Upon receipt of the CS II Material:

1) The CCSC must record on their copy of the DEA 222 Form, the number of containers (Packages Shipped) and the dates upon which those packages were received by 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:



CALIFORNIA INSTITUTE OF TECHNOLOGY

CONTROLLED SUBSTANCES MANAGEMENT PROGRAM
UNIFIED DISTRIBUTION, TRANSFER, AND DISPOSAL FORM

FORM REVISION DATE 3/28/16

DISTRIBUTION OF CS TO AUTHORIZED PERSON/RESEARCH GROUP

AUTHORIZED PERSON:	SMITH, JANE (EXAMPLE ONLY)			RESEARCH GROUP:	SMITH GROUP
BUILDING:	Broad	ROOM:	B220A	IACUC/AUTHORIZATION #:	1427-17
CIT CONTROL NUMBER	9999			INVOICE NUMBER	DEA 222: 45579700 EXP: 02/2023
GENERIC NAME	Etorphine			0033476255	
CS NAME	Etorphine			PO NUMBER	
CONTAINER	10 ml Vial			S390973	
CONCENTRATION UNITS	10 mg/mL			SUPPLIER	
SCHEDULE	CS-11			ZOOPHARM	
DATE OF DELIVERY	01-JUN-20				
DELIVERY:					
NAME:	Smith, John	SIGNATURE:		DATE:	06-JUN-20
RECEIVED BY:					
LAB A.P.:	Smith, Jane	SIGNATURE:		DATE:	06-JUN-20

3) When the UDTD forms have been printed and signed by the LCSC and the CCSC, attach a photocopy of the DEA 222 Form 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. A copy of the DEA 222 form should be attached to the PO, and a copy saved separately. 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. DEA 222 Forms for Reverse Distribution

- When CS Schedule II are released to a reverse distributor vendor, the vendor will issue a DEA 222 form. These DEA 222 Forms should be kept with the DEA Form 41 and maintained pursuant to the records retention requirements for the DEA Form 41.