



Inspection - Research Use of a Controlled Substance

Name of Registrant: _____

Building: _____ Room (Storage) #: _____ Room (Use) #: _____

Audited by: _____ Audit date: _____ Participants: _____

Applicable Sections (21 CFR 1300)	Registration	Yes	No	N/A	Comments
Registration (Part 1301)	<p>Does the person possess a current DEA registration?</p> <p>Schedule I-Registration: DEA Registration #: _____ Address listed on the registration: _____ _____ Specify Issue Date: _____ Specify Expiration Date: _____</p> <p>Schedule II-V-Registration DEA Registration #: _____ Address listed on the registration: _____ _____ Specify Issue Date: _____ Specify Expiration Date: _____ Note schedules of controlled substances covered under registration: _____</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

	Is the current registration (s) for the audit site kept on site?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Schedule I Location of storage: _____ same as DEA address Location of use or administration: _____ same as DEA address Schedule II-V Location of storage: _____, same as DEA address Location of use or administration: _____, same as DEA address				
	Are there any compounds on the premises and/or activities being performed that are not supported by the current registration?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Temple Policy	Have there been any inspections conducted by the DEA or other regulatory agencies? If yes, document who, when and results of the inspection. _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	EHR's controlled substances registration is available?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Has the registrant and all authorized users received Controlled Substance Training?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Security Requirements (Part 1301.71-1301.76)	Security Requirements	Yes	No	N/A	Comments
	Are the physical security controls for the storage area (substantially constructed safe or steel cabinet) that contain/hold any controlled substance in compliance with Part 1301.75? <ul style="list-style-type: none"> • Schedule 1-locked, substantially constructed safe (vault or GSA class 5 rated safe or cabinet) anchored to the floor or wall (if less than 750 lbs)? • Schedule II-V- locked, substantially constructed safe 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Are all storage cabinets' key-locked doors with separate keys? (spring locks or combination dial are not acceptable)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

	Is Access/Key to approved storage cabinet/safe is maintained under the control of the Registrant and/or designated authorized users?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Does the location of the safe or cabinet have limited access during normal work hours and secured after hours?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Are all controlled substances requiring refrigeration stored in locked containers securely fastened with a refrigeration unit?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Employee Screening (Part 1301.90-1301.93)	Authorized Users	Yes	No	N/A	Comments
	Has the registrant conducted a security and background check on all individuals working under their registration prior to granting authorization as an authorized user?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Is there a current written list (Authorized User Log) of authorized users under the registration?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Responsibilities and authorization of all authorized user is written and documented?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Loss/Diversion (21 CFR 1301.76)	Loss/Diversion Reports	Yes	No	N/A	Comments
	Are there any documented situations of unaccounted loses or potential diversion of product? If yes, was it reported to the local DEA office, Temple Campus Safety Services and EHRS? _____ If yes, was a DEA Form 106 filed? (specify situation) _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Are the accountability systems sufficient to quickly detect loss or diversion?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Records and Reports Of Registrants (Part 1304)	Records and Inventories	Yes	No	N/A	Comments
	Are all records maintained and readily retrievable on site for 24 months (21 CFR 1304.04(a))? <ul style="list-style-type: none"> • DEA Certificate of Registration • Authorized Users background checks • Authorized Users Log Books • Acquisition and Ordering invoices\packing slips • DEA Form 222 (used, voided and unused) • Inventory Records 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

<ul style="list-style-type: none"> ○ Initial inventory ○ Biennial inventory ○ General inventory • Transfer records • Disposal Records • Report of Loss or Theft Records (Form 106) 				
Are all records and inventories of schedule I and II controlled substances kept separately from those of schedule III-V (21CFR 1304.04 (g))?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are all the records and inventories of schedule III-V controlled substances kept separately from all other records of the registrant in such a form that the records are retrievable (21CFR 1304.04 (g))?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Does all the required inventories reflect all material “on hand”? Please note if the inventory reflects being taken on the opening of the business day or the close of the business day. Indicate if it does not state either (21 CFR 1304.11(a)).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is an initial inventory on site (21 CFR 1304.11 (b))?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Has a Biennial (every 2 year) inventory been conducted within the last 24 months of the last inventory date (21 CFR 1304.11(c))? Date of last inventory: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
With regards to changes in the re-scheduling of a controlled substances, are there any compounds handled at the audit site that were re-scheduled and are either not included in an initial inventory at the time of being re-scheduled or are not part of the biennial inventory(21 CFR 1304.11 (d)) ? If so, specify compounds and nature of schedule change and date.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is a general inventory of all controlled substances available on-site? Is there a separate record for each container? Is there a unique number or code upon receipt to assist with tracking? 21 CFR Part 1304 If no, are inventory methods compliant with 21 CFR Part 1304.22 (c) ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

	<p>For all drugs in current inventory and for all drugs used since last biennial inventory, is there a record of purchase or invoice?</p> <ul style="list-style-type: none">• Name, address and DEA registration number of supplier?• Name, concentration or weight, dosage form, and quantity of controlled substance received?• Signature of the person receiving the shipment (must be registrant or authorized agent)?• Date received? <p>For Schedule I and II Copy of the triplicate DEA form 222 must be completed and kept on file.</p> <p>Is the record of purchase readily available for inspection?</p> <p>Can every container purchased be accounted for?</p>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
	<p>Are any controlled substances transferred to and/or received by another registrant?</p> <p>If yes, for Import/Export, did the registrant follow the DEA permit application and declarations?</p> <p>If yes, for transfer within the University is there a record of the transfer?</p> <ul style="list-style-type: none">• Name, address, and DEA registration number of the recipient <hr/> <ul style="list-style-type: none">• Name, address, and DEA registration number of the supplier <hr/> <ul style="list-style-type: none">• Name, concentration, and quantity of controlled substance transferred <hr/> <ul style="list-style-type: none">• Transfer Date: _____	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	

	For Schedule I and II: Copy of three DEA form 222 must be completed and kept on file				
Orders Forms (Part 1305)	Purchasing	Yes	No	N/A	Comments
	Are only the registrant or authorized users placing orders for controlled substances (schedule I and II must be placed only by the registrant)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Are blank/unexecuted DEA 222 forms secured in a locked or restricted access area?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	For Schedule I or Schedule II drugs, has drug receipt been recorded on copy of DEA form 222 ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Destruction and/or Disposal (Part 1307)	Destruction and/or Disposal	Yes	No	N/A	Comments
	Review all destruction records for last two years. Note any inconsistencies. Have all unused and/or expired material returned to the manufacturer, supplier or processed through a "Reverse Distributor"?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Is on-site destruction is performed, confirm that DEA authorization is in place (ex. letter in the files)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	If off-site destruction is performed (ex-transport to incinerator, reverse distribution, etc.) is performed, have all the DEA stipulations (Forms, approvals, etc.) been met?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	