FLORIDA ATLANTIC UNIVERSITY

FAU Controlled Substances Program

Investigator Preparation Checklist

- **Print clearly in ink only**
- **Retain for 2 years following the last entry.**

DEA Registrant: _____ Building/Room: _____

Controlled Substance Licensing and Registration			
21 CFR 1301	**Yes**	**No**	**Comments/Action**
Does the PI possess a current State of Florida (FL) Department of Business and Professional Regulation (DBPR) exemption for use of controlled substances in research			
Is the FL DBPR exemption present on site or readily available?			
Does the address on the FL DBPR exemption correspond with the laboratory address and room number where the controlled substances are used?			
Does the PI possess a current US Drug Enforcement Administration (DEA) 225 researcher registration or DEA 224 practitioner registration?			
Is the DEA 223 Certificate of Registration Form 223 present on site or readily retrievable?			
Does the address on the DEA registration correspond with the laboratory address and room number where the controlled substances are stored?			
Are research activities within the scope of the FL DBPR exemption and DEA registration?			
Have copies of the FL DBPR exemption and DEA registration been forwarded to FAU EH&S?			
Inventory Records (Initial, Annual, Biennial, Closing)			
21 CFR 1304	Yes	No	Comments/Action
Was an initial inventory performed (new DEA registrations or address change)?			
Are the initial, annual and DEA biennial inventory records for the last two years on site?			
Was an FAU annual inventory performed and emailed to EH&S?			
Are schedule I-II inventory records kept separate from schedule III-V inventory records?			

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Were exact inventory quantities and amounts reported for schedule I-II controlled substances?			
Was a closing inventory performed (moving, transferring, retiring)?			
Usage Records (General Inventory, Multi-dose, Diluted Solution)			
21 CFR 1304	Yes	No	Comments/Action
Are the usage records (logs, general inventory) for the last two years retained on site?			
Are the usage records kept with the controlled substances in the lock box/safe?			
Are the usage records for schedule I-II substances kept separate from the usage records for schedule III-V substances?			
Were the general inventory and usage records recently reconciled for accuracy?			
Are waste amounts signed by both the DEA registrant (or authorized agent) and an EH&S witness?			
Are individual containers or packages labeled with a unique identifier to assist in usage record tracking?			
Do multi-dose vials have their own usage log?			
Do diluted solutions of controlled substances have their own usage log?			
Does the general inventory document transfers of expired or unneeded controlled substances to EH&S for disposal or destruction?			
Invoice and Purchase Records			
21 CFR 1305	**Yes**	**No**	**Comments/Action**
Are supplier invoices for controlled substances readily retrievable?			
Are supplier invoices for schedule I-II controlled substances kept separately from supplier invoices for schedule III-V controlled substances?			
Do all invoices contain the following: Name, address, DEA registration numbers of supplier and purchaser, order date, drug names, strengths, container forms and quantities received?			
Are all invoices signed and dated upon receipt or delivery?			

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DEA form 222 (Schedule I and II Order Forms)			
21 CFR 1305	**Yes**	**No**	**Comments/Action**
Are unused and executed DEA Form 222s stored in a locked and secured location?			
Are unused or executed DEA Form 222s readily retrievable?			
Are there any missing DEA Form 222s? If so, have missing forms been reported to the West Palm Beach District DEA Office?			
Do unused DEA Form 222s with mistakes or those returned from supplier have "VOID" marked across the form?			
Are all executed DEA Form 222s signed by the DEA registrant?			
Do all schedule I or II shipments have a corresponding DEA Form 222?			
Are all copy 3 (Purchaser) section of executed DEA Form 222s complete and accurate?			
Disposal			
21 CFR 1317	**Yes**	**No**	**Comments/Action**
Are expired or unneeded controlled substances kept in a substantially constructed cabinet until disposal?			
Are all disposal forms and DEA Form 222s associated with disposal kept on site?			
Were non-recoverable waste amounts properly disposed of?			
Are non-recoverable waste amounts documented in the inventory or usage record with two signatures (DEA registrant or authorized agent and one witness)?			
Loss or Theft			
21 CFR 1301.76	**Yes**	**No**	**Comments/Action**
Have all actual or suspected cases of theft or significant loss been reported to FAU EH&S, FL DBPR and DEA?			
Was a DEA Form 106 submitted for actual or suspected cases of theft or significant loss?			
Have losses incurred during shipment been reported to the supplier?			
Are non-recoverable losses documented in inventory or usage record with two signatures (authorized agent and witness)?			

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Security			
CFR 1301.71 – 1301.93	**Yes**	**No**	**Comments/Action**
Have policies or standard operating procedures been developed by the laboratory with respect to storage, administering and record keeping of controlled substances?			
Are the controlled substances stored in a securely locked, substantially constructed cabinet or safe that is anchored to a wall or the floor?			
Is the storage cabinet located at the address (building and room) as identified on the FL DBPR exemption and the DEA registration?			
Does the controlled substance storage location have minimal traffic flow?			
Is the lab or room with the storage cabinet locked when the registrants or authorized agents are not present?			
Are controlled substances requiring refrigeration securely stored or locked in a refrigerator?			
Is access to controlled substances kept to a minimal number of authorized agents?			
Are keys to the controlled substance storage cabinet locked up or secured when not in use?			
Do the locks on the storage room and cabinet have the capability to be reset or rekeyed if an authorized agent resigns, is terminated or a loss or theft is suspected?			
Is an authorized personnel log kept on site?			
Is the authorized personnel log updated frequently?			
Have background checks been performed on authorized agents and authorized personnel?			
Have all authorized agents read and signed the “FAU Controlled Substance Employee Questionnaire?”			
Are all screening statements complete and kept on site?			
Are controlled substances delivered directly to a receiving individual in the laboratory?			

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