Controlled Substances

Overview of Policy, Responsibilities, and Changes

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Overview

1. Regulatory Requirements
2. DEA Schedules and Codes
3. Controlled Substance Program Elements
4. BFB-BUS 50 Controlled Substance Policy
5. Changes and updates to the UC Controlled Substances Program
    - DEA Registrations and Departmental Model Implementation
    - Controlled Substance Use and Human Subjects Research
    - Power of Attorney and Delegations

Federal Regulations for Controlled Substances

Controlled Substances Act - 1970

Title 21 CFR Part 1300 - end

Drugs or chemicals whose manufacture, use, and possession are regulated by the government.

DEA Schedule Numbers and Codes

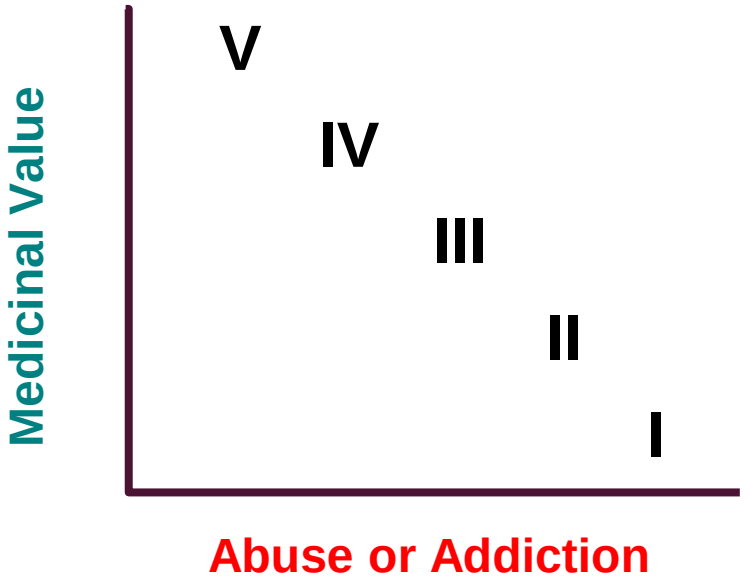
Labels & Identification

Schedule numbers I – V

Medicinal value, harmfulness, potential for abuse or addiction

Schedule numbers with a “Y” in the narc column denote a narcotic

4 digit codes identify specific drugs



	Potential for Abuse	Accepted Medical Use	Potential for Addiction
Schedule I	High	None	Drug is not safe to use, even w/ medical supervision
Schedule II	High	Yes, sometimes allowed with restrictions	Abusing the drug can cause severe physical and mental addiction
Schedule III	Medium	Yes	Abusing the drug can cause severe mental addition, or moderate physical addiction
Schedule IV	Low	Yes	Abusing the drug may lead to mild mental or physical addiction
Schedule V	Lowest	Yes	Abusing the drug may lead to mild mental or physical addiction

Common Controlled Substances Used in Research

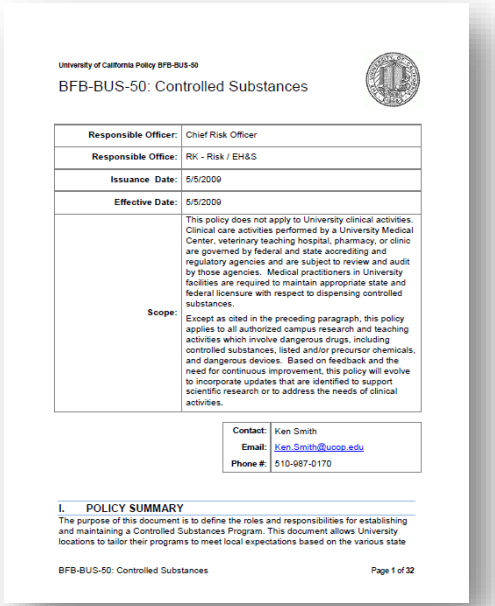
Substance	Schedule	Narc	DEA Code
Ketamine	III	N	7285
Pentobarbital	II	N	2270
Buprenorphine	III	Y	9064
Fentanyl	II	Y	9801
Diazepam	IV	N	2765

Marijuana and Related Compounds

Substance	Schedule	Narc	DEA Code
Marihuana (cannabis)	I	N	7360
Marihuana extract (CBD)	I	N	7350
Approved Cannabidiol Drugs	V	N	7367
Dronabinol (Marinol)	III	N	7369

Controlled Substances Program
Elements

BUS-50 Controlled Substances Presidential Policy - May 2009



University of California Policy BFB-BUS-50

BFB-BUS-50: Controlled Substances

Responsible Officer:	Chief Risk Officer
Responsible Office:	RK - Risk / EH&S
Issuance Date:	5/5/2009
Effective Date:	5/5/2009
Scope:	This policy does not apply to University clinical activities. Clinical care activities performed by a University Medical Center, veterinary teaching hospital, pharmacy, or clinic are governed by federal and state accrediting and regulatory agencies and are subject to review and audit by those agencies. Medical practitioners in University facilities are required to maintain appropriate state and federal licensure with respect to dispensing controlled substances. Except as cited in the preceding paragraph, this policy applies to all authorized campus research and teaching activities which involve dangerous drugs, including controlled substances, listed and/or precursor chemicals, and dangerous devices. Based on feedback and the need for continuous improvement, this policy will evolve to incorporate updates that are identified to support scientific research or to address the needs of clinical activities.

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I. POLICY SUMMARY

The purpose of this document is to define the roles and responsibilities for establishing and maintaining a Controlled Substances Program. This document allows University locations to tailor their programs to meet local expectations based on the various state

BFB-BUS-50: Controlled Substances Page 1 of 32

Why

What

How

Who

BUS-50 Controlled Substances Summary

Why

Develop and maintain a Controlled Substances Program.

Does NOT apply to University clinical patient care.

- Hospitals
- Pharmacy
- Narcotic Treatment Programs
- Veterinary Medicine

Does apply to campus **research** and **teaching** activities which involve dangerous drugs, including **controlled substances**, listed and/or precursor chemicals, and dangerous devices.

BUS-50 Controlled Substances Summary

What

Establishes the minimum regulatory requirements and provides a *Best Practices Guide* to aid in program implementation.

Key Elements

- DEA Registration
- Authorization/Training
- Storage
- Ordering, Delivery, and Receipt
- Usage Logs and Inventory
- Transfers of CS
- Import and Export Policies
- Disposal of CS
- Diversion, Theft and Loss reporting
- Illicit Activities and Repercussions
- Personnel Screening Requirements

BUS-50 Controlled Substances Summary

How

University locations are expected to:

- Implement a CS program using the *Best Practices Guide.*
- Develop detailed written procedures.
- Comply with federal and state regulations on acquiring, maintaining, storing, using, and disposing of controlled substances.

BUS-50 Controlled Substances
Key Roles

Who

Responsible Official (RO)

Has responsibility for oversight at the location.

Controlled Substances Program Administrator (CSPA)

RO's designee charged with implementing and managing the CS program on a day-to-day basis.

Typically managed centrally in EH&S.

Controlled Substances program management and compliant research involves numerous entities within UC:

Research Affairs
Research Personnel
Procurement
Security
IACUC
IRB
Hospital Pharmacy
EH&S

UC Campus Controlled Substances Programs Overview
Schedule II – V

Campus/ Location	PIs with Research Authorizations	Authorized Personnel	Research Registrations	Registration Type
UC Berkeley	46	199	1	Campus
UC Davis	186	729	4	Campus, Individual
UC Irvine	159	638	22, 1	Departmental, Practitioner
UC Los Angeles	91	331	26	Departmental
UC Merced	9	19	1	Campus
UC Riverside	50	171	2	Research Teaching
UC San Diego	253	1476	46	Departmental
UC San Francisco	244	1212	2, 5	Campus, Individual
UC Santa Barbara	11	43	11	Individual
UC Santa Cruz	15	70	2	Campus
LBNL	3	40	3	Individual

Key DEA Regulation – Separate Registrations for Separate Locations

21 CFR § 1301.12

- DEA contends despite “general physical location” language that “location” means building or address not campus
- Main issue in U of Michigan $4.3 million settlement involving CS transfers to off campus clinics that had state licensure but not DEA registrations
- Main issue driving campus designation process at UC

Key DEA Regulation – Theft & Significant Loss Reporting

21 CFR § 1301.76

- Notify DEA field office in writing of theft or significant loss within one business day of discovery
- Complete and submit electronic DEA Form 106
- “Significant loss” depends on six different factors
- Second significant factor in U of Michigan settlement -- security & dispensing system reports showed theft/loss but not reported

Key DEA Concept – Closed System of Distribution

- Established schedules
- Registration
- Established quotas
- ARCOS “Automated Reports and Consolidated Ordering System”
- Security Requirements
- Record Keeping Requirements
- Cyclic Investigations

DEA Registrations
Campus Shift to Departmental Model

Background

- DEA challenged one UC location's institutional research registration
- Similar challenges occurred at two other UC locations in the past
- Institutional registration of two other major CA hospital / universities in LA Division challenged

DEA Registrations
Campus Shift to Departmental Model

DEA Interpretation & Enforcement

Inconsistent nationally and regionally

LA & SD DEA moving away from institutional registrations, SF DEA allowed

Stanford / Cal-Tech have institutional registrations

Two UC locations well-developed departmental models

No documented approval for departmental model

Our location challenged due to change in DEA personnel

DEA Registrations
Campus Shift to Departmental Model

DEA's Regulatory Theory

Institutional research registration and central receipt of CS violates:

5% transfer rule: distribution vs dispensing

Separate Registrations for Separate Locations

Our Counter-Argument

UC emphasized:

Research registration permits distribution as coincident activity

"Location" broadly defined to include geographic location

DEA Registrations
Campus Shift to Departmental Model

DEA original position:

Obtain 250 individual PI registrations

No centralized receipt

UC contacts DEA HQ:

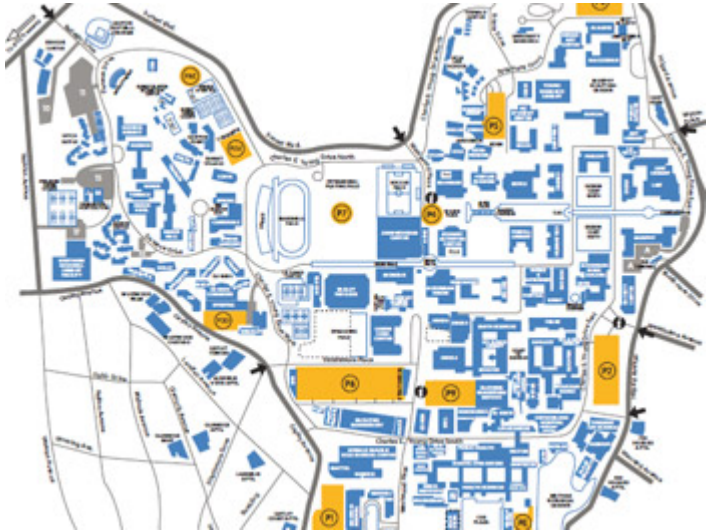
April meeting with 3 CA DEA divisions and DEA HQ

DEA directs UC:

Adopt departmental model systemwide

No more institutional registrations; individual registrations OK

DEA Registrations
Campus Shift to Departmental Model



Departmental Model / Campus Designation

Two Step Process:

1. File Dept Registration for Schedule II – V CS with DEA
   - "Department" more broadly defined
   - Only covers contiguous property
2. File Campus designation request with DEA HQ
   - Template request approved by DEA HQ
   - Local DEA follows up and reviews location's P&Ps
   - DEA provides written confirmation of approval

DEA Registrations
Campus Shift to Departmental Model

Structural v. Nuts and Bolts

Departmental model arises from disagreement over regulatory requirements

University locations have done well on recent audits

- ✓ Procurement
- ✓ Storage
- ✓ Recordkeeping
- ✓ Diversion / Theft
- ✓ Disposal

DEA Registrations
Campus Shift to Departmental Model Challenges

Resource Issues

↑ Requirements ↑ Registrations

CSPAs at 0.25 or 0.5 FTE re CS duties

SF DEA will monitor our NorCal UC locations closer

- FOIA issues
- IACUC protocols for Schedule II-V
- Strategies to avoid production & reduce risk

DEA Registrations
Campus Departmental Model Issues

Departmental Model Implementation Questions

Timeline for departmental model?
Local DEA P&P review for campus designation request?
Remote locations require their own receipt?

Stricter compliance with Regulations
DEA Liaison & Policy Written Guidance

BUS-50 Controlled Substances
Human Research

BUS-50 Current State - Human Subjects

Practitioners must be licensed

IRB approval must be obtained

CSPAs have limited interaction with HR (therapeutic or non-therapeutic) practitioners relying on individual registration

BUS-50 Controlled Substances Human Research

Hospital Pharmacy

CS Prescription

Practitioner

Practitioner ordinarily relies on individual practitioner or researcher registration.

BUS-50 Controlled Substances Human Research

Internal Controls

Hospital pharmacy transfers via patient-specific prescription.

Pharmacy and hospital P&Ps.

OHRPP P&Ps.

IRB reviews and approves protocol.

External Controls

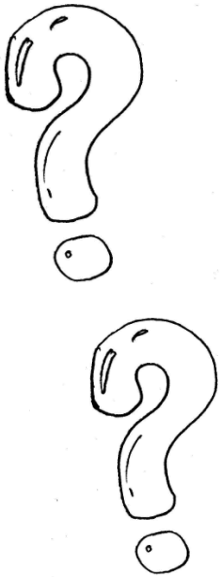
FDA review of investigational new drug application.

BUS-50 Controlled Substances
Human Research

Questions about Controls of CS in Human Research

1. CS use consistent with IRB protocol?
2. Investigator supervises CS administration?
3. Who ensures CS is not diverted?
4. How is recordkeeping and inventory tracked?
5. Is there confirmation unused CS returned?
6. Are security and storage requirements adequate?

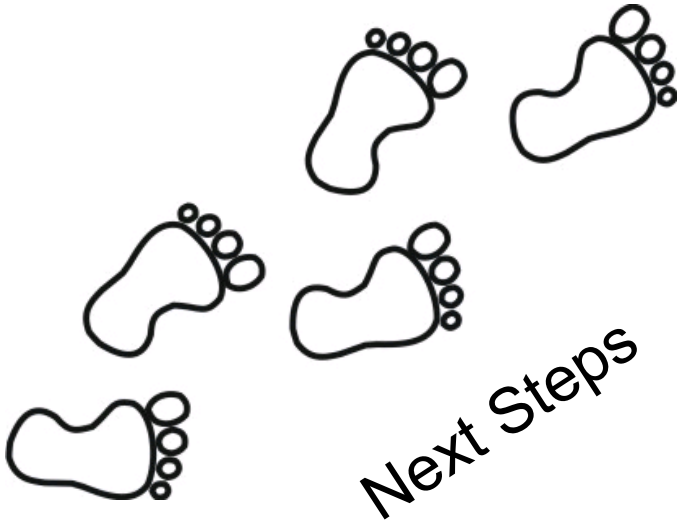
BUS-50 Controlled Substances
Human Research



More Questions Regarding Monitoring Controls…

7. Who else monitors / oversees CS use in human research particularly post-dispensing? OHRPP?
8. What other controls besides licensure and IRB approval can be added to BUS-50?
9. Should we require practitioner to rely on research registration instead of practitioner registration?
10. Are practitioners ordering CS from distributors instead of pharmacy?

BUS-50 Controlled Substances Human Research



Discuss and implement CS requirements and oversight for CS use in Human Research in BUS-50

Campus Research Schedule I Issues

These areas are evolving – reach out to CSPA or counsel or Office of Research/RPAC or ECAS:

- Research involving cannabis or hemp or support from marijuana related businesses: https://www.ucop.edu/research-policy-analysis-coordination/policies-guidance/cannabis/index.html
- Research involving CBD
- Research involving Analogues
- Manufacturing of CS

Campus Research v. Clinical Oversight of CS

Similarities

- Many of the DEA rules are identical or similar such as different locations & theft and significant loss reporting rules

Differences

- CSPA and EH&S v. Chief Pharmacy Officer
- JCAHO & Pharmacy Board Controls on Clinical Side
- Clinical Side Has More CS Volume but Also More Stringent Storage, Recordkeeping & Disposal
- More DEA Audits & Oversight for Campus Research

Diversion in the Clinical Space

Drug Diversion and Impaired Health Care Workers

- Drug diversion is a potential threat to patient safety in every organization.
- Risks to patients include:
  - Inadequate pain relief
  - Exposure to infectious diseases from contaminated needles and drugs
  - Death
- Drug diversion by health care workers cause problems for both patients and the organization to include:
  - Undue suffering by patient's who do not get pain relief from the intended medication
  - Substandard care or patient harm due to impairment
  - Damaging reputation
  - Major civil and criminal monetary penalties

Diversion in the Clinical Space

Drug Diversion Statistics by Health Care Workers

- According to the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) and the American Nurses Association (ANA), about 10 percent of heath care workers are abusing drugs.

  - Risk factors include:
    - High availability and access to controlled substances
    - Occupational hazards/stresses
    - Pre-existing injury

Diversion in the Clinical Space

The Drug Enforcement Administration (DEA) recognizes five classes of drugs that are frequently abused:

- Opioids (Fentanyl, Oxycodone, Hydrocodone)
  - Fentanyl – One of the most potent opioids, is the most commonly diverted
  - Diversion of opioids has been seen across all levels of the organizations, from chiefs to the frontline staff, and across all clinical disciplines.
- Depressants (Diazepam, Alprazolam)
- Hallucinogens (Ketamine)
- Stimulants (Adderall, Concerta)
- Anabolic Steroids (Testosterone)

Diversion in the Clinical Space

Leaders have a responsibility to establish processes that support staff while enabling the rapid detection of diversion. Patterns and trends that indicate potential diversion include:

- Controlled substances are removed
  - With no physician's order
  - For patients not assigned to the health care worker
  - For recently discharged or transferred patients
  - Unresolvable inventory discrepancies
- Controlled substance vials/syringes tampered with
- Controlled substance waste is not adequately witnessed
- Controlled substance waste in syringe is replaced with saline

Diversion in the Clinical Space

Essential Components of a CS Diversion Prevention Program

- Core administration elements include:
  - Legal and regulatory requirements
    - Ensure proper licensing of facilities
    - Ensure proper record keeping practices
    - Follow proper diversion reporting guidelines
  - Organization oversight and accountability
    - Dedicated diversion response team
    - Dedicated diversion auditor
    - UC Controlled Substance Collaborative Team (UCD, UCI, UCLA, UCSD, UCSF)

Diversion in the Clinical Space

- System-level controls include:
  - Human resources management
    - Employee assistance programs
    - Disciplinary actions
  - Automation and technology
    - Video monitoring in high-risk areas
  - Monitoring and surveillance
    - EPIC Reports, RxAuditor, Pandora, CareFusion Knowledge Portal, Bluesight, DVx
  - Investigation and reporting

Diversion in the Clinical Space

- Provider-level controls include:
  - Chain of custody
    - Proper tracking and documentation of controlled substances
  - Storage and security
    - Policies and procedures for storage of controlled substances
  - Internal pharmacy controls
    - Separation of duties
  - Prescribing and administration
  - Returns, waste, and disposal

Diversion in the Clinical Space

- Staff should be educated about the CSDPP including leadership oversight, legal and regulatory requirements, monitoring and surveillance, automation and technology, and pharmacy controls.
- The organization must foster a culture of staff empowerment to stop, question, and report possible diversion.
- Health care workers must be expected and empowered to speak up when something seems abnormal or safe.

Summary

- Controlled Substance programs are complex and highly regulated
- Compliant use of controlled substances vital for UC research enterprise
- Program, policy, and interactions with DEA are going through changes and updates
  - BUS-50 revisions may include clinical and human research CS oversight
  - Continuing challenges in implementing campus departmental registration
  - Campus Research Schedule I issues can be complex and require guidance
  - Improving policies & practices to combat CS diversion in clinical enterprise