Controlled Substances in the Lab Environment

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Who are we?

- James Pitcher, CPA – Senior Internal Auditor, UIHC
  - Anesthesia
  - College of Dentistry
- Staci Meade, CPA, MAC – Internal Auditor, UIHC
  - College of Pharmacy
  - Controlled Substances
Objectives

1. Research Lab Environment
2. Drug Diversion Examples
3. Controlled Substances Schedule and Desirable Drugs
4. Case Study
5. Controlled Substances Testing Criteria and Common Control Issues
6. Internal/External Examinations
7. University of Iowa Monitoring Structure
Environment

- Controlled drugs used in research and stored in labs
- Research goals often higher priority than controls
- Buy-in from multiple levels of institution required to maintain effective controls
- Similar research, shared access
Auburn University
June 2, 2015

• Lab Technician arrested for selling Gamma Hydroxybutyric Acid (GHB) – a date rape drug

• Six-month investigation, sells to undercover agents
Emory University Hospital Midtown, GA – March 8, 2016

- One million controlled substances diverted over four years via poor billing controls
- Hospital to pay a $200,000 fine to state Pharmacy Board
- Pharmacy license on probation for three years
### Controlled Substances Schedules

<table>
<thead>
<tr>
<th>Schedule Type</th>
<th>Description</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>High potential for abuse and no accepted medial use</td>
<td>Heroin, LSD, marijuana, ecstasy, methaqualone, and peyote</td>
</tr>
<tr>
<td>II</td>
<td>High potential for abuse and dependence</td>
<td>Oxymorphone, Pentobarbital, Morphine, Vicodin, Meth, Ritalin, Fentanyl, Oxycodone, Hydrocodone, Codeine</td>
</tr>
<tr>
<td>III</td>
<td>Moderate to low potential for dependence</td>
<td>Ketamine, Buprenorphine, Euthasol®, Anabolic Steroids, Testosterone</td>
</tr>
<tr>
<td>IV</td>
<td>Low potential for abuse and dependence</td>
<td>Xanax, Soma, Darvon, Valium, Ambien, Tramadol</td>
</tr>
<tr>
<td>V</td>
<td>Lower potential for abuse and dependence</td>
<td>Robitussin, Lomotil, Motofen, Lyrica, Parepectolin</td>
</tr>
</tbody>
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Case Study

- Give audience a chance to find controls in an example.
- Debrief
Case Study Debrief

1) Drugs improperly stored – must be behind dual-lock safe or locked at all times
2) State and federal license should be maintained on site – not just by credentialing office
3) Non-scheduled drugs should not be stored with controlled substances. If institution requires non-scheduled to be secured (Propofol), must be stored separately.
4) Disposal of drugs requires registrant be present and to provide witness signature on documentation
5) Use logs should be updated in real time to ensure accuracy
6) Each controlled substance should have a separate use log – not combined

7) Laboratory should have initial drug inventory when laboratory is established and biennial inventories thereafter

8) Unless Principle Investigators are working on same project, controlled substances should be labeled with the separate registrants names – not shared between experiments

9) All purchasing records should be maintained onsite

10) Transportation procedures should be documented and kept onsite. Only drugs to be immediately used should be transported and should be in non-transparent container during transport.

11) Authorized lab users should be documented in a list and updated in real time for hires and terminations
Testing Criteria

- Institutional Governance
  - Who is ultimately responsible for development and enforcement of policies?
  - Is the research community aware of the reporting lines?
  - What punitive action can be taken for violations?
  - What are the monitoring procedures?

- Institutional Policies
  - Will vary by institution
  - Should be at least as stringent as the State and Federal regulations
Testing Criteria (cont’d)

- Documentation
  - State and Federal Licenses
  - Initial and Biennial Inventory
  - Purchasing and Disposition
  - Power of Attorney/ Designation of Authority
  - Daily Distribution Log for each controlled substance
  - Standard Operating Procedures to Transport
Testing Criteria (cont’d)

- Access/Authorized User Log
  - Only staff that need access
  - Must be updated in real time
  - Reviewed periodically

- Physical Security
  - Dual locked safe
  - Access to operating room/area

- Transportation Procedures
  - Must be documented in an SOP
  - Hard copy of SOP on site
Need both state Board of Pharmacy license and federal DEA license

Must obtain state license before DEA (federal) license

Licensing process takes time – researchers may procrastinate

Tempting to use fellow researcher’s controlled substances
Common control issues in Labs

- Using a filing cabinet to store drugs instead of a dual-lock safe
- Generic access to labs, including areas with controlled substances
- Bags of controlled substances that are not properly stored
- Documentation not completed timely and/or completely
Internal and External Laboratory Examinations

- Internal Examinations
  - Institutional Animal Care and Use Committee
  - Environmental Health and Safety
  - Research Compliance

- External Examinations
  - DEA
  - State Pharmacy Boards
  - Build a rapport
  - Be mindful of agent turnover
University of Iowa Controlled Substance Monitoring Structure

- Twenty-page Laboratory Guideline for Managing Controlled Substances in Research Laboratories
- Controlled Substances webpage with required forms and FAQ prepared by Environmental Health & Safety
- Controlled Substance Specialist monitors all drug use of hospital using AccuDose software
- Controlled Substances Committee – for response to misappropriation and implementation of new controls
Questions?