Effectively Managing and Monitoring Controlled Substances in Research

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Emmelyn Kim is the AVP, Research Compliance and Privacy Officer at Northwell Health. She oversees the research compliance programs including quality assurance, conflict of interest and regulatory affairs. She has been involved in research for over 17 years and began her career in the field working as a clinical research coordinator for NIH and industry sponsored cardiovascular and diabetes studies at Northwestern University and Joslin Diabetes Center. She has a MA, from Boston University, MPH from Columbia University’s Mailman School of Public Health, and is certified in healthcare research compliance and as a clinical research associate.

Dr. Ji-Eun Kim is a Research Pharmacist at Northwell Health where she is involved in reviewing the management of investigational drugs in clinical research and provides operational consultation and education. In addition, she provides regulatory support for Investigational New Drug Applications and Expanded Access Use and participates in audits. Prior to joining Northwell Health in 2013, she worked in Research Pharmacy at the NYPH-Columbia University Medical Center and the NYU Langone Medical Center. She has a PhD in Biological Engineering with an emphasis in Applied Biosciences and both a Master’s and Bachelor’s degree in Pharmacy.

Topics

1. Key regulatory and policy considerations for laboratory, animal and clinical research programs
2. Working effectively with environmental health and safety, researchers, security, pharmacy and administration on controlled substance management in research
3. How to integrate controlled substance reviews into your compliance program
1. Key regulatory and policy considerations

Considerations

• Research programs
• Territories covered by programs
• Oversight & operational infrastructure
• Research strategy, growth and industry trends
Considerations for Institutional Policy

- Regulatory requirements
- Recommendations for clinical vs. non-clinical
- Individual vs. institutional license/registration
- Procurement, storage & final disposition
- Institutional procedures and forms
- Stakeholder responsibilities

Key Policy Elements

- Purpose, Scope & Definitions
- Procedures
  - Roles & Responsibilities
  - Institutional notification
  - License and registration/authorized individuals
  - Procurement, transport
  - Documentation, recordkeeping, inventory
  - Storage, access
  - Dispensation
  - Suspected diversion, loss or theft
  - Disposal, destruction, wastage
- Auditing and monitoring expectations
- References to other policies, forms, etc.

Schedules of Controlled Substances

- Schedule 1
- Schedule 2
- Schedule 3
- Schedule 4
- Schedule 5

- Abuse potential
- Psychological/physical dependence
Federal & State Requirements

| Authorization | • DEA  
|              | • State  
| Security     | • Schedule-specific  
|              | • Authorized personnel  
| Procurement  | • Schedule-specific  
|              | • Authorized personnel  
| Maintenance  | • Accountability  
|              | • Inventory  
| Reporting    | • Theft & significant loss  
|              | • State prescription monitoring program  
| Disposal     | • Revenue distributor  
|              | • Drug waste  

Special Requirements for Institutional License/Registration

• Limited to departments or units requiring use of controlled substances for many ongoing protocols  
• Schedules II-V only  
• Needs to have adequate resources and staff for oversight, management and supervision of activities and reporting requirements  
• Institutions may limit this type of license/registration

Special Regulatory Requirements for Schedule 1 Controlled Substances

Federal Reviews  
Regulatory Approvals  
State Authorization  
DEA Registration
2. Working effectively with stakeholders

Who are your stakeholders?

- Researchers
- Facilities
- Pharmacy
- EHS
- Procurement
- Security
- Research Administration
- Compliance
- FDA
- DEA Field Office
- State Regional Office

Stakeholders May Differ Based on the Research

- Preclinical
  - Laboratories
  - Animal Facility
- Clinical
  - Pharmacy
  - PI Site (ambulatory)
Researchers

Provide training & guidance on regulatory requirements
- Sponsor, federal agency requirements (e.g. IND)
- Regulatory approvals (e.g. IRB, IACUC)
- State research license & DEA registration
- Required institutional forms, records, reporting

Facilitate process
- Storage and dispensing location
- Resources and procedures
- Authorized individuals
- Coordination with stakeholders

In-person meeting, guidance documents and templates

Clinical Researchers

Sponsor-Investigator (IND Holder)

IND Submission to FDA
- Regulatory Approval
- State Authorization
- DEA Registration

PI (external IND sponsor study)

Guidance, Templates & Support
Communication
Guidance & Coordination

Clinical Research

If utilizing pharmacy services
- Communicate with pharmacists
- Ensure they are aware of policies and have SOPs
- Perform protocol or programmatic reviews

If storing CS at the research site
- Ensure they have adequate resources, storage & security
- Provide a review of drug handling and documentation
- Perform protocol specific reviews
Preclinical Research

If utilizing centralized services
- Ensure service has SOPs and aware of policies
- Ensure they have ongoing monitoring
- Perform programmatic reviews

If storing CS in the labs
- Ensure they have adequate resources, storage & security
- Set documentation requirements
- Perform protocol specific reviews

Coordination with Other Departments

Security
- Assess security risks
- Assist with security planning, controls and reporting

Environmental Health and Safety
- Establish procedures: spills, breakage, loss, reverse distribution, local disposal, transport, etc.

- Collaboration on policies and procedures
- Coordination tailored for sites and protocols

Institutional Level Approvals & Reviews

- Clinical, animal and laboratory research regulatory vs. institutional approvals
- Researcher onboarding and exit process
- Compliance touch points
3. How to integrate controlled substance reviews into your compliance program

Factors for Risk Evaluation

**Research/Registrant**
- Research activity type
- CS schedule and type
- Knowledge/experience level

**Facility/Security**
- Storage location and controls
- Access and transport
- SOPs

Monitoring During Study Conduct

**Initiation stage**
- Review requirements for processes and documentation
  - Provide Ad-hoc in-services for remedial purposes
  - Develop education, guidance document and tools

**Active stage**
- Conduct audits
  - Provide continuous guidance

**Completion stage**
- Conduct audits
  - Provide guidance on study closure (e.g., IP final disposal)
Compliance Program

Consultation and planning
• Ensure appropriate notifications from stakeholders

Routine and for-cause audit & investigations program
• Cover full spectrum of research
• Ensure appropriate staffing, SOPs, reporting structure

Diversion Identification
• Evaluate data (e.g., automatic dispensing machine reports)
• Ensure escalation processes tied to various departments

Education & training
• Develop education based on audit findings
• Provide education in various formats & based on role

Policy development
• It’s a cycle: review, feedback & dissemination

Work plans
• Use risk assessments, plan reviews based on high risk areas and upcoming research

Ongoing collaboration with stakeholders is key!

Contact Information

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Thank You

Any questions?