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.

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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

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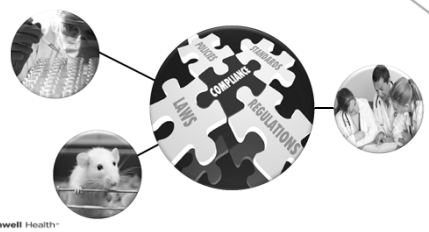
1. Key regulatory and policy considerations



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Considerations

- Research programs
- Territories covered by programs
- Oversight & operational infrastructure
- Research strategy, growth and industry trends

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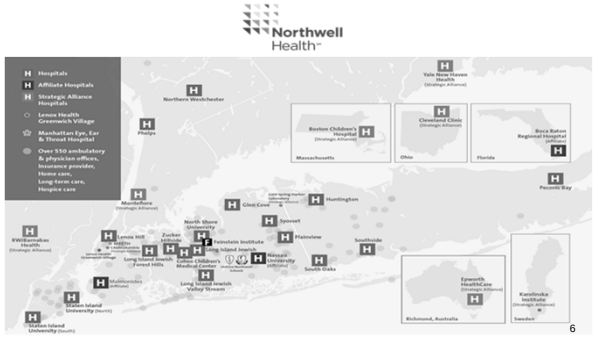

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Considerations for Institutional Policy

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

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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.

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Schedules of Controlled Substances

- Abuse potential
- Psychological/physical dependence

Schedule 1 | Schedule 2 | Schedule 3 | Schedule 4 | Schedule 5

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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	• Reverse distributor • Drug wastage

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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

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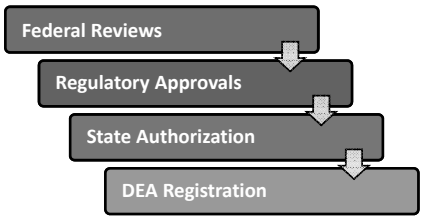
Special Regulatory Requirements for Schedule 1 Controlled Substances



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2. Working effectively with stakeholders

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Who are your stakeholders?

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

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Stakeholders May Differ Based on the Research

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

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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

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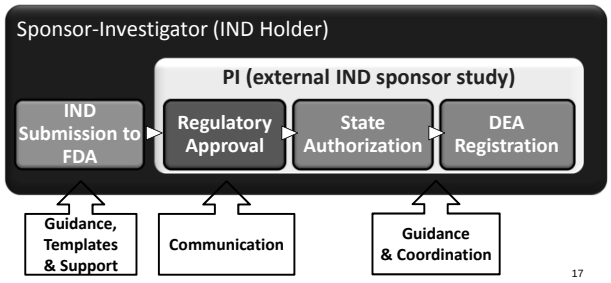
Clinical Researchers



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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

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Preclinical Research

If utilizing centralized services	If storing CS in the labs
• Ensure service has SOPs and aware of policies • Ensure they have ongoing monitoring • Perform programmatic reviews	• Ensure they have adequate resources, storage & security • Set documentation requirements • Perform protocol specific reviews

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Coordination with Other Departments

Security	Environmental Health and Safety
• Assess security risks • Assist with security planning, controls and reporting	• Establish procedures: spills, breakage, loss, reverse distribution, local disposal, transport, etc.

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

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Institutional Level Approvals & Reviews

Laboratory Animal Research Program	Research Administration	Clinical Research Program

- Clinical, animal and laboratory research regulatory vs. institutional approvals
- Researcher onboarding and exit process
- Compliance touch points

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3. How to integrate controlled substance reviews into your compliance program

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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

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Monitoring During Study Conduct

Initiation stage	Active stage	Completion stage
• Review requirements for processes and documentation	• Conduct audits • Provide continuous guidance	• Conduct audits • Provide guidance on study closure (e.g., IP final disposal)

- Provide *Ad-hoc* in-services for remedial purposes
- Develop education, guidance document and tools

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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

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Compliance Program

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!

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Contact Information

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Thank You

Any questions?