



# Controlled Substances and Dangerous Drugs Compliance: Building Blocks for Success



EMORY  
UNIVERSITY

Office of Research Integrity and Compliance  
Research Compliance and Regulatory Affairs

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ORIC TEAM:

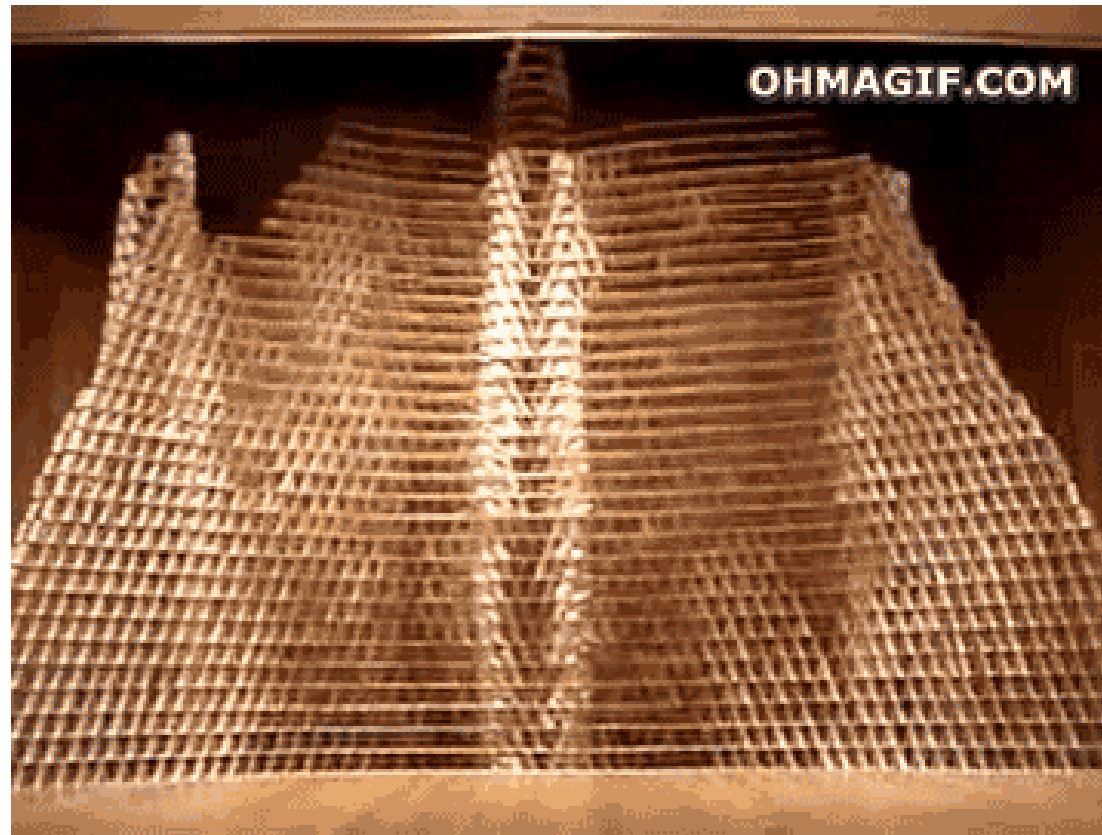
DANISHA BLOSSAT

MARIA DAVILA

MARGARET HUBER

Expecting compliance without a proper foundation is like...

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**Building a house with a deck of cards!**

In this  
presentation

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Why compliance matters

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The law

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Responsibilities of the  
Registrants

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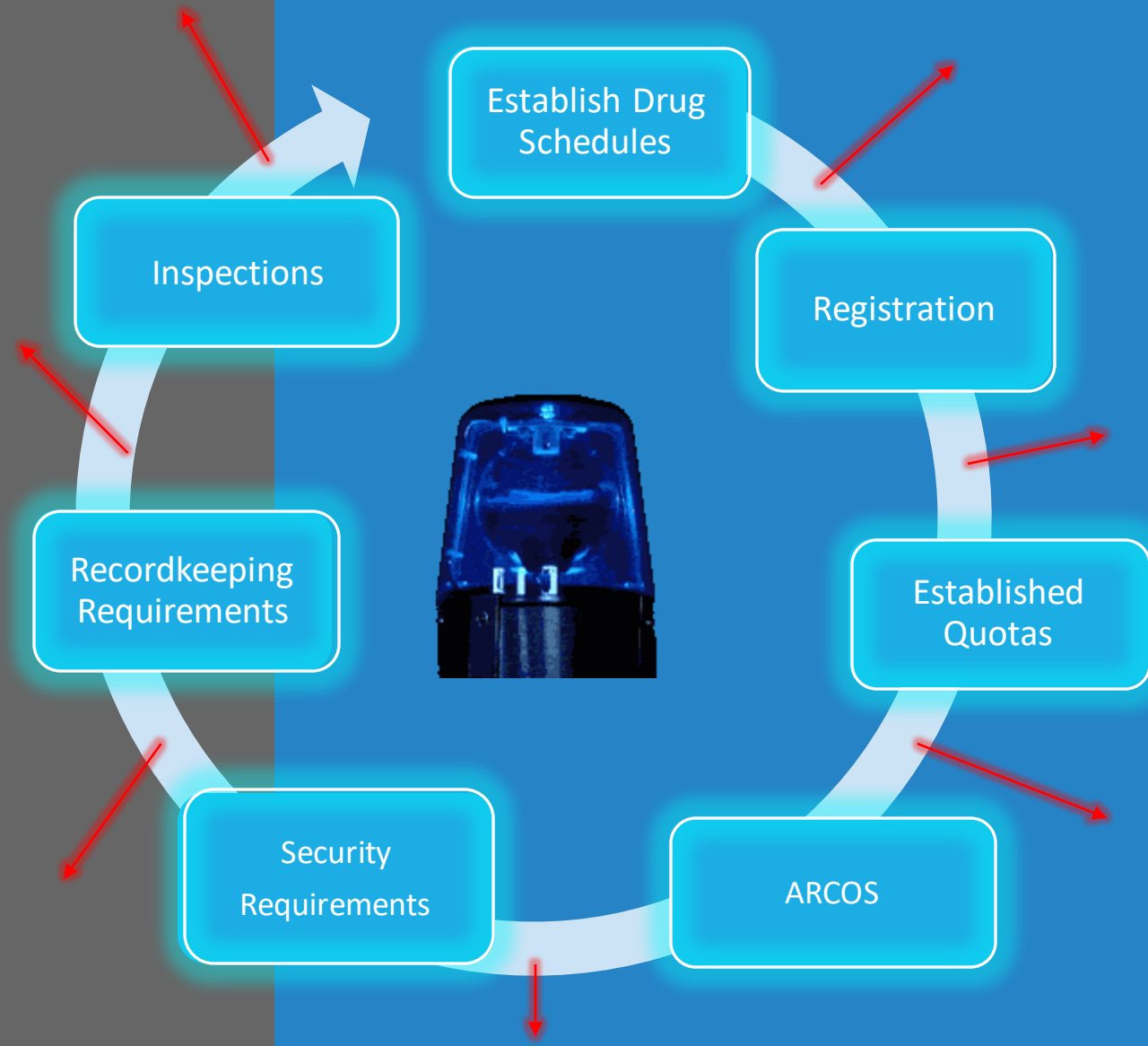
Ongoing Training

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# Why does compliance matter?



The Federal and State Regulations are designed to operate within a closed system of distribution for the protection of public health safety and to prevent the **diversion** of controlled substances into the illicit market.

Drug diversion is the **illegal distribution or abuse/use of prescription drugs** away from the intended end user or a legitimate source.

Each Registrant must do what the law requires so that the drugs stay in the closed system of distribution and the drugs are not diverted onto the streets!

Drug Diversion:  
It would never  
happen here!

99% of the time Diversion happens  
from the inside.

The #1 reason - People's life  
circumstances change in an instant

What is Diversion?

Diversion Case Review



# What is Diversion?

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Drug diversion is the illegal distribution or abuse of prescription drugs or their use for purposes not intended by the prescriber.

# Every Employee has a responsibility to report

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## **Every employee has a responsibility to report diversion.**

Reports of drug diversion by fellow employees is not only a necessary part of an overall drug security program but also serves the best interest of the public. DEA requires that an employee who has knowledge of diversion by a fellow employee report the information either to DEA or an Emory official. Emory will treat all reports as confidential and will take all reasonable steps to protect the confidentiality of the information and the identity of the employee reporting the information.

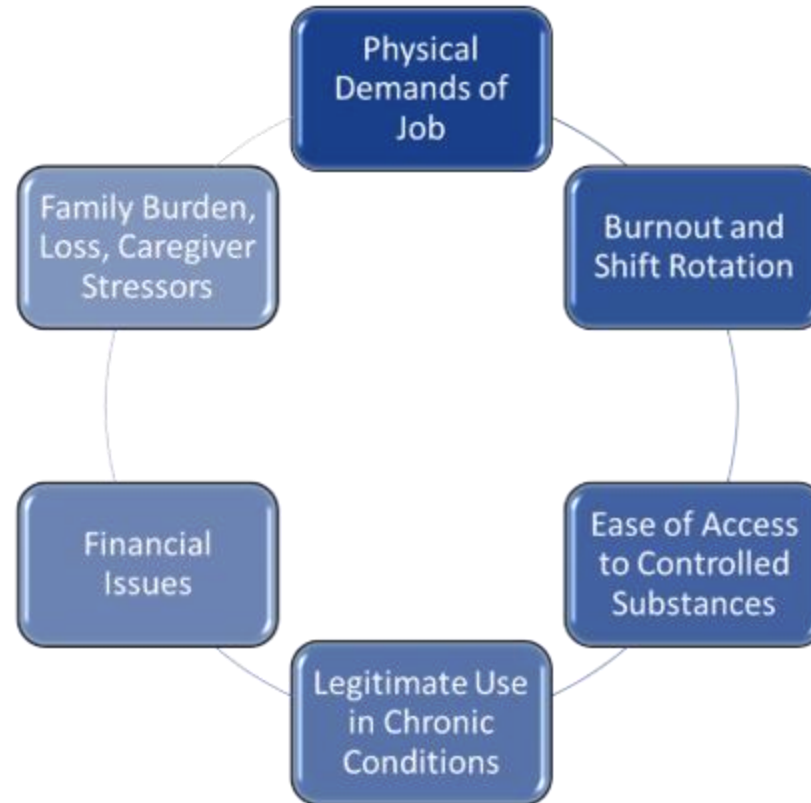
Employees who don't feel comfortable reporting to their Supervisor/Department Head or HR may report to the Office of Research Integrity and Compliance ([ORIC@emory.edu](mailto:ORIC@emory.edu)) or they may contact the EMORY TRUST LINE. The Trust Line is operated by an independent third party who will maintain the caller's anonymity while ensuring that the caller's report is routed to the proper individuals within the University. Contact the Emory Trustline:

CALL: 888.550.8850

ON THE WEB: [EmoryTrustLine.com](http://EmoryTrustLine.com)

# Occupational and Personal Risk Factors that may lead to diversion

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# Common behaviors associated with drug diversion

The following behaviors may be associated with drug diversion:



It's important to avoid unintentional or unconscious bias.

- Suspicion does not automatically equate to diversion.
- Good employees are not immune to diversion.



April 28, 2023  
Contact: [redacted]

For Immediate Release

For Immediate Release



August 30, 2018

For Immediate Release

Contact: Brian McNeal

Phone Number: (571) 362-1498

## Drug Enforcement Administration

Orville O. Greene  
Special Agent in Charge

Detroit  
[@DEADetroitDiv](#)

# Record settlement reached in University of Michigan hospital drug diversion civil penalty case

**DETROIT** - The Drug Enforcement Administration and United States Attorney's Office for the Eastern District of Michigan today announced that the University of Michigan Health System has agreed to pay the United States **\$4.3 million** as part of a settlement resolving allegations that UMHS violated certain provisions of the Controlled Substances Act, 21 U.S.C. §§ 801-904. The settlement, which is civil in nature, resulted from a years-long Drug Enforcement Administration investigation of UMHS's handling of controlled substances. It is the nation's largest settlement of its kind involving allegations of drug diversion at a hospital.

DEA began its investigation after two tragic incidents occurred in December 2013 involving two UMHS employees – a nurse and an anesthesiology resident. Both overdosed on opioids, including fentanyl, at a UMHS facility. The nurse's overdose was fatal.

dispensing  
with saline solution be



stances to respond to emergencies.  
fentanyl vials to the locked narcotics supply cabinet and  
tampered with the  
and replaced the drug with a clear

RALEIGH, N.C. – A former Fuquay-Varina nurse was sentenced today to 48 months



<https://emorywheel.com/drugs-scam-costs-university-health-system-millions/>

## The Law: Regulatory Requirements

Federal Requirements (DEA  
Registrants only)– 21 CFR Part 1300  
to end

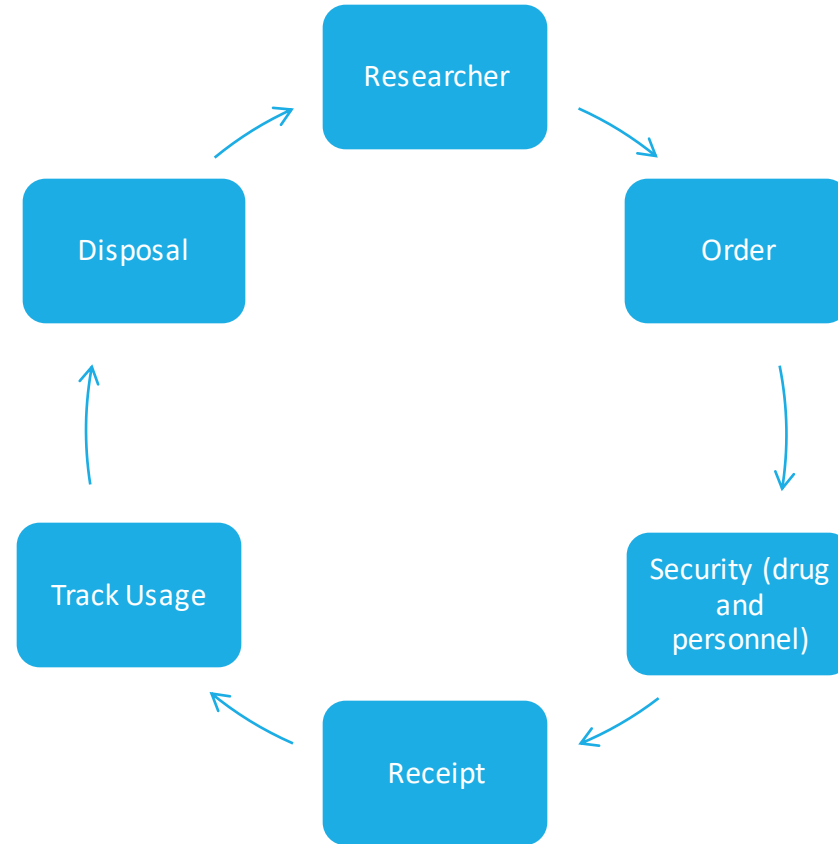
State Regulations (All Registrants) –  
O.C.G.A Title 16, Chapter 13, Articles  
1-3, O.C.G. A Rule 480-7-04

Each licensee is responsible for  
knowing and complying with all the  
regulations required by the license.

# Researcher Responsibility:

Keeping drugs inside the closed system of distribution

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# 100% Compliance

Due Diligence	Diversion Awareness	Standards	Policy
Proper Recordkeeping	Drug Accountability	Procedures	Reporting
Know the Laws & Penalties	Understand <u>ALL</u> the Regulations	Registration	Security Requirements

# Future Training Topics:

- Obtaining Proper Licensing – Pre-Registration Assistance & Proper Security
- What do I do once I receive my license? Setting up my drug binders
- What's a controlled substance and what's a dangerous drug?
- How do I conduct an Inventory? (Initial, Biennial or Annual)
- Ordering and Receiving Drugs Properly
- Current Use Forms. Which forms do I use?
- Disposing of Drug Properly
- Maintaining Drug Accountability
- Theft/Loss Reporting? It is a BIG Deal!
- Who do these controlled substances belong to? Abandoned drugs
- Conducting Self Inspections
- What happens when I retire or leave Emory?

Register for Training Sessions here:

[Meeting Registration - Zoom](#)



**MANAGING CONTROLLED SUBSTANCES & DANGEROUS DRUGS IN RESEARCH**

Come learn how to manage your drugs and ask your pressing questions!

Presented by the Office of Research Integrity and Compliance (ORIC)  
part of Research Compliance and Regulatory Affairs (RCRA)

## Managing Controlled Substances & Dangerous Drugs in Research

Date & Time

You can choose to attend one or more of the following sessions.

- Nov 8, 2023 12:00 PM
- Dec 13, 2023 12:00 PM
- Jan 10, 2024 12:00 PM





# Our contact info

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Office email: [oric@emory.edu](mailto:oric@emory.edu)

Office Website: <https://rcra.emory.edu/oric/index.html>

**Maria Davila**

**Email:** [maria.davila@emory.edu](mailto:maria.davila@emory.edu)

**Phone:** [404-712-8676](tel:404-712-8676)

**Margaret Huber**

**Email:** [mhuber@emory.edu](mailto:mhuber@emory.edu)

**Phone:** [404-727-2233](tel:404-727-2233)

**Danisha Biossat**

**Email:** [danisha.biossat@emory.edu](mailto:danisha.biossat@emory.edu)

**Phone:** 404-251-1216



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Thank you!  
Any Questions?



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