Managing Research Compliance Utilizing an Electronic Compliance Database System

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Disclosure

• I have no financial relationships to disclose

• The electronic compliance manager tool I will be highlighting was developed by the Department of Pharmacy Services for Intermountain Healthcare, Inc., and is a copyright of Intermountain Healthcare, Inc.

• Electronic database is currently active in use for pharmacy compliance

• Conceptually applicable to the research setting, medication research in proposal

• Presentation is to highlight conceptually how an electronic compliance manager can be used in a research compliance environment.

Why is compliance so important to research?

• Protect and provide safety
  • Public / Patient Safety
  • Investigator Safety
    • Ex., drug study involving hazardous medication
  • Standing as a reputable investigator

• Protect the data
  • Integrity of the study
  • Increases the impact of the research outcome

• Regulatory
  • Controlled substances
  • Government and regulatory oversight (FDA, JC, HHS, etc.)

• Cost control
### Common Reasons for Research Non-Compliance

- **Pre-study Related**
  - Failure to conduct complete literature research, prior literature reports
  - Failure to have a detailed, written and vetted protocol
    - sample size analysis
    - statistical assumptions to be made
    - identification of measurement methods
    - identify adequate bias control measures
    - failure to determine and write a detailed time line
- **IRB Approval**
  - Adherence to responsibilities as clinical investigator
    - No approval obtained, lapse in IRB, no continuing review
- **Study Related**
  - Informed Consent (improper/outdated consent)
  - Protocol Deviations / Violations (changes made with no approval)
  - Drug and Device Accountability (record keeping inadequate)
  - Inadequate Medical Records (trial data not recorded (e.g., adverse events)

### Compliance in Research: It’s About Coordination

- **Manual Oversight**
  - Costly
  - Time consuming
  - Accuracy lower
    - data collection errors
    - competency of staff
    - study integrity harder to control
  - Bulky
    - paperwork and amount of filing
    - ability to retrieve more difficult
- **Electronic Oversight**
  - Less costly
  - Increased efficiency
  - Realtime
  - Compliance assessment and controls improved

### RxCM: Electronic Compliance Manager

- Stores Documents associated with task completion and documents compliance.
- Organizes workflow daily/weekly/monthly for staff
- Provides both corporate/local levels a method for managing compliance
  - Status assessment in real time
  - Ensures completion of required job functions for category compliance
- Provides validation tool for compliance audits/inspections.
  - Internal (Internal/Process Control, Corporate Compliance, Internal Quality)
  - External (State DOPP, DEA, FDA, JC, etc.)
RxCM: Electronic Compliance Manager

**RxCM Functionality**

- Standardized reports
- Custom reports
- Notification of upcoming tasks
- Notification of tasks requiring follow-up

**Maintains Task Lists by category to complete/perform in compliance with the required category**
- Corporate Assigned Tasks
- Local Pharmacy Assigned Tasks (created by the pharmacy)

**Organizes required categories of compliance in the workplace**
- Controlled substances
- Compounding USP 797/795
- Pharmacy licensing
- 340B
- Utah State DOPL Readiness
- Medication Management (JC)
- Medication Research
- In 2017, 640 medication research studies

**Next Steps for Pharmacy Compliance → Medication Research Compliance**

**Food and Drug Administration Good Clinical Practice Guidelines state:**

4.6 Investigational Product(s)

4.6.1 Responsibility for Investigational Products

Where allowed/required, the investigator/institution may/should assign some or all of the investigator's/institution's duties for investigational product accountability at the trial site(s) to an appropriate pharmacist or another appropriate individual who is under the supervision of the investigator/institution.

**The Joint Commission Medication Management Standard: MM.06.01.05**

Rationale: The hospital safely manages investigational medications

A.3. The hospital has a written process addressing the use of investigational medications that includes review, approval, supervision, and monitoring.

A.5. The hospital’s written process for the use of investigational medications specifies that the pharmacy controls the storage, dispensing, labeling, and distribution of investigational medications.
• The use of an electronic compliance database manager provides an efficient method for coordinating, managing, and documenting aspects of compliance for related activities in the health-care setting.

• An electronic compliance database manager provides a tool to organize activities of compliance, tailored to the demands required based on the setting or project being conducted.

• The use of an electronic compliance database manager provides the compliance specialist the ability to organize, validate, audit, report, trend, and assess all research compliance requirements in a healthcare setting.