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
    • identify limitations 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  • Informed Consent (improper/outdated consent)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
    - Real time
  - Compliance assessment and controls improved

RxCM: Electronic Compliance Manager

- Stores Documents associated with task completion and documents compliance.
  - Attachments can be added to each task for documentation, retrieval, verification
  - Demonstrate compliance with internal policies as well as State/Federal laws

- Dashboard function provides timeline alerts for task completion
  - 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 DOPL, DEA, FDA, JC, etc.)
RxCM: Electronic Compliance Manager

- RxCM Functionality

<table>
<thead>
<tr>
<th>Reports</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Standardized reports</td>
<td>• Notification of upcoming tasks</td>
</tr>
<tr>
<td>• Custom reports</td>
<td>• Notification of tasks requiring follow-up</td>
</tr>
</tbody>
</table>

- Maintains Task Lists by category to complete/perform in compliance with the required category
  - Corporate Assigned Tasks
    - Controls/organizes compliance for categories of focus system wide
  - Local Pharmacy Assigned Tasks (created by the pharmacy)
    - Controls/organizes workflow for task completion by staff

- 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
Medication Research

• 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 product(s) accountability at the trial site(s) rests with the investigator/institution.
  4.6.2 Where allowed/required, the investigator/institution may/should assign some or all of the investigator's/institution's duties for investigational product(s) 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 1. The hospital has a written process addressing the use of investigational medications that includes review, approval, supervision, and monitoring.
  A 2. 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.

RxCM: Electronic Compliance Manager

• © 2017 Intermountain Healthcare, All rights reserved A Central APEX Application, version: 1.92
Login

Sign in to Application

Username: 
Password: 
Sign in

Pharmacy Compliance Manager is a tool created to track compliance with Intermountain Policy as well as State and Federal laws.

- How can I get access to this application?
- Who do I call for help?

Main Screen

Task List | Manage Tasks | Maintenance | Dashboard | Reports

Task List

Category | Status | Title | Frequency | Type | Assigned To | Due Date
--- | --- | --- | --- | --- | --- | ---
Research and Development | Deferred | Regulatory documentation is complete (all aspects must be complete and accounted for to complete the task), any variations not to be reported | Unassigned | 04/10/2017 | Just-One | Corporate
Drug and Device accountability compliance has been developed in compliance with PDE requirements and by Pharmacy oversight (all aspects must be complete and accounted for to complete the task), any variations not to be reported | Unassigned | 04/10/2017 | Just-One | Corporate
Site Operations have been approved (Inspected), found to be appropriate for the study protocol all aspects must be complete and accounted for to complete the task | Unassigned | 04/10/2017 | Just-One | Corporate
Due Today | Regulatory Review completed and uploaded into SCM | Unassigned | 04/10/2017 | Just-One | Corporate
Due Today | Study protocol and application submitted for IRB review and approval | Unassigned | 04/10/2017 | Just-One | Corporate
Due Today | Study approved by IRD? | Unassigned | 04/10/2017 | Just-One | Corporate
Due Today | Study protocol and application reviewed by Pharmacy Services for pharmacy oversight determination | Unassigned | 04/10/2017 | Just-One | Corporate
Due Today | Drug and Device accountability compliance has been developed in compliance with PDE requirements and by Pharmacy oversight (all aspects must be complete and accounted for to complete the task), any variations not to be reported | Unassigned | 04/10/2017 | Just-One | Corporate
Due Today | Regulatory Documentation is complete (all aspects must be complete and accounted for to complete the task) | Unassigned | 04/10/2017 | Just-One | Corporate
Due Today | Regulatory Review completed and uploaded into SCM | Unassigned | 04/10/2017 | Just-One | Corporate
Due Today | Drug and Device accountability compliance has been developed in compliance with PDE requirements and by Pharmacy oversight (all aspects must be complete and accounted for to complete the task), any variations not to be reported | Unassigned | 04/10/2017 | Just-One | Corporate
Due Today | For controlled substances, protocol and pharmacy oversight measures are developed for compliance with regulatory standards (all aspects must be complete and accounted for to complete the task), any variations not to be reported | Unassigned | 04/10/2017 | Just-One | Corporate
Due Today | Regulatory Review completed and uploaded into SCM | Unassigned | 04/10/2017 | Just-One | Corporate
Task List Function

### Pharmacy (Research location/facility)

- Assigned to: All Pharmacy Tasks
  - Unassigned
  - CS Techs
  - Group name-renamer
  - Jensen, Michael
  - Shoe, Jim
  - Water, April
  - Doe, John
  - Doe, Jane

### Category (Study)

- A.S. Evaluations
- CMO Auditing
- Acu Dose Tracking
- CS Monitoring
- Canada
- Cindy's Test Category
- Cindy's Test Category
- Controlled Substance Monitoring
- Opioids
- Directory Verification
- General
- Homecare CS Monitoring
- Matts Test Category
- Medical Group
- Outpatient
- Inspections
- Research and Development
- Rx Specific Category
- Shadr stuff
- Task
- Training Pharmacy Task Categories
- Compounding

#### Task List Function

<table>
<thead>
<tr>
<th>Task</th>
<th>Description</th>
<th>Assigned To</th>
<th>Due</th>
<th>Completed</th>
<th>Frequency</th>
<th>Type</th>
<th>Last Updated</th>
<th>Notes</th>
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</thead>
<tbody>
<tr>
<td>Due</td>
<td>Regulatory documentation is complete (all aspects must be complete and accounted for to complete the task)</td>
<td>Unassigned</td>
<td>01/16/2017</td>
<td>Yes</td>
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<td>Corporate</td>
<td>04/05/2017</td>
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<td>Due</td>
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<td>04/05/2017</td>
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</table>
### Main Screen

**Task List**

- **Pharmacy**
- **Research Compliance**

**Assigned To**

- All Pharmacy Tasks

**Category**

- Research and Development

<table>
<thead>
<tr>
<th>Category</th>
<th>Status</th>
<th>Title</th>
<th>Assigned To</th>
<th>Due</th>
<th>Completed</th>
<th>Frequency</th>
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<tr>
<td>Research and Development</td>
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<td>04/10/2017</td>
<td>04/12/2017</td>
<td>Just One</td>
<td>Corporate</td>
<td>Jensen, Michael</td>
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<td>Completed List</td>
<td>Regulatory Documentation is complete (all aspects must be complete and accounted for to complete the task)</td>
<td>Unassigned</td>
<td>04/10/2017</td>
<td>04/12/2017</td>
<td>Just One</td>
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<td>Jensen, Michael</td>
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<tr>
<td>Completed List</td>
<td>Site Operations have been approved/expected, found to be appropriate for the study protocol (all aspects must be complete and accounted for to complete the task)</td>
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<td>04/12/2017</td>
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<td>Jensen, Michael</td>
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<tr>
<td>Completed On-Time</td>
<td>Regulatory Forms completed and updated into PICM</td>
<td>Unassigned</td>
<td>04/10/2017</td>
<td>04/12/2017</td>
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<td>Corporate</td>
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<tr>
<td>Completed On-Time</td>
<td>Study protocol and application submitted for IRB review and approval?</td>
<td>Unassigned</td>
<td>04/10/2017</td>
<td>04/12/2017</td>
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<td>04/10/2017</td>
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<td>-</td>
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</tbody>
</table>
Manage Tasks Function

- Create Task

Regulatory review for controlled substances study and compliance with all State and Federal regulations is completed and uploaded to the task.

Entered By Michael Jensen Entered 5/4/2017
Updated By Michael Jensen Updated 5/4/2017
Maintenance Function

- **Add New**

  ![Add New Button]

- **Edit**

  ![Edit Button]

**Pharmacy**

- **Pharmacy**: [Input Field]
- **Start Date**: [Input Field]
- **End Date**: [Input Field]

**Task List**

- Add New Edit

**Maintenance Task Categories**

- Pharmacies
- Task Categories
- Admin Users
- Scanners
- Holidays

**Task List**

- Maintenance
- Dashboard
- Reports

**Task Categories**

- 340B Auditing
- Acceptance Testing
- CS Monitoring
- Cindy’s Test Category
- Delta
- Directory Verification
- Filtermore Task List
- General
- Homecare CS Monitoring
- Matts Test Category
- Medical Group
- Outpatient/Inpatient
- Research and Development
- Shani Stuff

**Task Information**

- Start Date: [Input Field]
- End Date: [Input Field]

**People**

- Last Name: [Input Field]
- First Name: [Input Field]
- Group: [Input Field]
- Add Group: [Input Field]

**Categories**

- Task Category: [Input Field]
- Owner: [Input Field]
Dashboard Function

- Dashboard

Reports Function
• Individual Study Reports

<table>
<thead>
<tr>
<th>Month</th>
<th>2015 Completion Rate by Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>April</td>
<td>96.0%</td>
</tr>
<tr>
<td>May</td>
<td>96.0%</td>
</tr>
<tr>
<td>June</td>
<td>96.0%</td>
</tr>
<tr>
<td>July</td>
<td>96.0%</td>
</tr>
<tr>
<td>August</td>
<td>96.0%</td>
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<tr>
<td>September</td>
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<tr>
<td>October</td>
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</tr>
<tr>
<td>November</td>
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<tr>
<td>December</td>
<td>96.0%</td>
</tr>
<tr>
<td>Grand Total</td>
<td>96.0%</td>
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</table>

2015 Completion Rate by Month

• Overall Compliance Report by Study

<table>
<thead>
<tr>
<th>Research Compliance by Study</th>
<th>Funding Source</th>
<th>Q1 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>G = Grant, P = Private, I = Industry</td>
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<td></td>
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<tr>
<td>Pre-Study Review/Task Completion</td>
<td>IRB</td>
<td>Site Study Task Performance Reports</td>
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<tr>
<td>G</td>
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<tr>
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</tr>
<tr>
<td>P</td>
<td>97.0</td>
<td>100.0</td>
</tr>
</tbody>
</table>

System Average: #NAME? 87 95 97 100

Red Level: <85 <81 <100 <100 <100 <85 <85 <100 <100 <85 <85 <100 <100 <100 <85
Conclusion

• 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.

Questions?