


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.


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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

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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 - Informed Consent (improper/outdated consent)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))

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Porter W, Surin C. Current challenges and opportunities in clinical research compliance. *October 1, 2006 Spring* 4(3):21-24
 Oak CD, Milligan B. Effectiveness of common mistakes encountered in clinical research. *1998; 10(1):13-14*

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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

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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.)

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RxCM: Electronic Compliance Manager

- RxCM Functionality

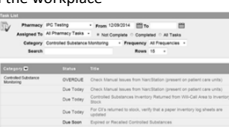
Reports	<ul style="list-style-type: none"> Standardized reports Custom reports
Email	<ul style="list-style-type: none"> Notification of upcoming tasks Notification of tasks requiring follow-up

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RxCM: Electronic Compliance Manager

- 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



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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.


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Good Clinical Practice: Consolidated Guidelines. Federal Register, 1997, Vol. 62, No. 90.




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



Item	Priority	Due	Frequency	Type
Compliance with regulatory standards (all aspects must be complete and accounted for to complete the task, any violations are to be reported?)	Urgent	04/15/2017	All Days	Compliance
Regulatory Documentation is complete (all aspects must be complete and accounted for to complete the task)	Urgent	04/15/2017	All Days	Compliance
Site Operations have been appropriately handled to be appropriate for the study protocol (all aspects must be complete and accounted for to complete the task?)	Urgent	04/15/2017	All Days	Compliance
Regulatory Review completed and updated into OCS	Urgent	04/11/2017	All Days	Compliance
Study protocol and application submitted for IRB review and approval?	Urgent	04/15/2017	All Days	Compliance
Study approved by IRB	Urgent	04/15/2017	All Days	Compliance
Study protocol and application submitted to Pharmacy Services for pharmacy oversight determination?	Urgent	04/15/2017	All Days	Compliance
Study protocol and application compliance has been developed in compliance with IRB requirements and all Pharmacy oversight (all aspects must be complete and accounted for to complete the task, any violations are to be reported?)	Urgent	04/15/2017	Weekly	Compliance
Regulatory Documentation is complete (all aspects must be complete and accounted for to complete the task)	Urgent	04/15/2017	All Days	Compliance
Regulatory Review completed and updated into OCS	Urgent	04/15/2017	All Days	Compliance
Compliance with regulatory standards (all aspects must be complete and accounted for to complete the task, any violations are to be reported?)	Urgent	04/15/2017	All Days	Compliance
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Regulatory Review completed and updated into OCS	Urgent	04/15/2017	All Days	Compliance



Main Screen

Category	Status	Title	Assigned To	Start	Completed	Frequency	Task	Last Modified
Research and Development	Completed	For controlled substances, protocol and pharmacy oversight measures are developed for compliance with regulatory standards of aspects must be complete and accounted for to complete the task. Are violations are to be reported?	Unassigned	04/10/2017	04/10/2017	Jul-Due	Research	04/10/2017
Research and Development	Completed	Regulatory Documentation is complete all aspects must be complete and accounted for to complete the task.	Unassigned	04/10/2017	04/10/2017	Jul-Due	Research	04/10/2017
Research and Development	Completed	Site Operations have been approved/inspected. Form to be appropriate for the study protocol all aspects must be complete and accounted for to complete the task?	Unassigned	04/10/2017	04/10/2017	Jul-Due	Research	04/10/2017
Research and Development	Completed	Regulatory Files completed and uploaded into iCRP	Unassigned	04/11/2017	04/11/2017	Jul-Due	Research	04/11/2017
Research and Development	Completed	Study protocol and application submitted for IRB review and approval?	Unassigned	04/11/2017	04/11/2017	Jul-Due	Research	04/11/2017
Research and Development	Due Soon	Study approved by IRB?	Unassigned	04/12/2017	-	Jul-Due	Research	04/12/2017
Research and Development	Due Soon	Study protocol and application reviewed by Pharmacy Services for pharmacy oversight determination?	Unassigned	04/12/2017	-	Jul-Due	Research	04/12/2017
Research and Development	Due Soon	Drug/Device or assembly conditions have been developed in compliance with IRB requirements and in Pharmacy oversight all aspects must be complete and accounted for to complete the task. Are violations are to be reported?	Unassigned	04/12/2017	-	Weekly	Research	04/12/2017
Research and Development	Due Soon	Regulatory Documentation is complete all aspects must be complete and accounted for to complete the task.	Unassigned	04/12/2017	-	Jul-Due	Research	04/12/2017
Research and Development	Due Soon	Regulatory Files completed and uploaded into iCRP	Unassigned	04/20/2017	-	Jul-Due	Research	04/20/2017
Research and Development	Due Soon	Drug/Device or assembly conditions have been developed in compliance with IRB requirements and in Pharmacy oversight all aspects must be complete and accounted for to complete the task. Are violations are to be reported?	Unassigned	04/20/2017	-	Jul-Due	Research	04/20/2017
Research and Development	Due Soon	For controlled substances, protocol and pharmacy oversight measures are developed for compliance with regulatory standards of aspects must be complete and accounted for to complete the task. Are violations are to be reported?	Unassigned	04/20/2017	-	Jul-Due	Research	04/20/2017

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Manage Tasks Function

Category	Status	Title	Start	End	Frequency	Last Modified	Assigned To	
Research and Development	Completed	For controlled substances, protocol and pharmacy oversight measures are developed for compliance with regulatory standards of aspects must be complete and accounted for to complete the task. Are violations are to be reported?	Jul-Due	04/10/2017	Research	04/10/2017	04/10/2017	
Research and Development	Completed	Regulatory Documentation is complete all aspects must be complete and accounted for to complete the task.	Jul-Due	04/12/2017	Research	04/12/2017	04/12/2017	
Research and Development	Completed	Regulatory Files completed and uploaded into iCRP	Jul-Due	04/11/2017	Research	04/11/2017	04/11/2017	
Research and Development	Completed	Site Operations have been approved/inspected. Form to be appropriate for the study protocol all aspects must be complete and accounted for to complete the task?	Jul-Due	04/10/2017	Research	04/10/2017	04/10/2017	
Research and Development	Completed	Study approved by IRB?	Jul-Due	04/12/2017	Research	04/12/2017	04/12/2017	
Research and Development	Completed	Study protocol and application reviewed by Pharmacy Services for pharmacy oversight determination?	Jul-Due	04/12/2017	Research	04/12/2017	04/12/2017	
Research and Development	Completed	Study protocol and application submitted for IRB review and approval?	Jul-Due	04/12/2017	Research	04/12/2017	04/12/2017	
Research and Development	Completed	Drug/Device or assembly conditions have been developed in compliance with IRB requirements and in Pharmacy oversight all aspects must be complete and accounted for to complete the task. Are violations are to be reported?	04/10/2017	04/20/2017	04/10/2017	Weekly	Research	04/10/2017

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Manage Tasks Function

Create Task

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Maintenance Function

Task List Manage Tasks Maintenance Dashboard Reports

Home » Maintenance » Task Categories

Maintenance Task Categories Add Category

Task Category	Start	End
3408 Auditing	19182014	
Accu-Dose Tracking	06052014	
CS Monitoring	07012014	
Cindy's Test Category	08052014	
Controlled Substance Monitoring	09152014	
Della	08272014	
Directory Verification	06052014	
Filmore task list	08272014	09012021
General	06052014	
Homecare CS Monitoring	12232014	
Meds Test Category	08012015	
Medical Group	09042014	
Outsourcing/Inspections	07262014	
Research and Development	04202017	08302017
Shad staff	09182014	

rows 1 - 15 of 18 Next >



Maintenance Function

• Add New Add New Edit Edit

Pharmacy Cindy's Test Pharmacy

Start Date 03/30/2017 End Date

Last Name	First Name	Groups	People	Task Category	Owner
Jensen	Mike	Add	Leach, Bruce	Cindy's Test Category	Pharmacy
Shoe	Jim	Add	Hoop Name - Name	Rx Specific Category	Pharmacy
Water	April	Add	1:2	Cash	Pharmacy
Doe	John	Add		3408 Auditing	Corporate
Doe	Jane	Add		Accu-Dose Tracking	Corporate
Nilly	Willey	Add		CS Monitoring	Corporate



Dashboard Function

Task List Manage Tasks Maintenance Dashboard Reports

• Dashboard

Task List

Pharmacy Cindy's Test Pharmacy Due Today

Assigned To All Pharmacy Tasks Not Complete Completed All Tasks

Category All Categories Frequency All Frequencies

Search Rows 200

Category	Task	Task Name	Frequency	Due	Frequency	Due
Accu-Dose	Accu-Dose Compliance Checklist		CS Test	02/10/2017	Daily	Corporate
Controlled Substance Monitoring	Perform Hazard, Diversion Detection Auditing Activities		CS Test	02/11/2017	Daily	Corporate
	Performing Accu-Dose Review (including the Non-Rx Item and Levels)		CS Test	02/17/2017	Daily	Corporate
	Validate the Receiving Process		CS Test	02/19/2017	Daily	Corporate
	Perform Accu-Dose Discrepancy by Station Invoice		CS Test	02/08/2017	Daily	Corporate
	Perform Accu-Dose Open Transaction Report/AR/AR Open Transaction Review		CS Test	02/11/2017	Daily	Corporate
	Using a weekly Assort Performance Analysis (ACS) report to highlight possible diversion		CS Test	02/13/2017	Daily	Corporate
PCR Operations	10% (up to 20%) test validation - all valid verification (PM 10%)		CS Test	02/08/2017	Daily	Corporate
	WAVE #1 - /r batch pre-accu-dose validation		CS Test	02/03/2017	Daily	Corporate
	WAVE #2 - /r batch pre-accu-dose validation		CS Test	02/07/2017	Daily	Corporate
	WAVE #3 - /r batch pre-accu-dose validation		CS Test	02/04/2017	Daily	Corporate
	WAVE #4 - /r batch pre-accu-dose validation		CS Test	03/08/2017	Daily	Corporate
	ESD/CDS joint validation initial		CS Test	03/05/2017	Daily	Corporate
Bank Computing	#1 Backup Replicate Pump (Bank)		CS Test	03/02/2017	Daily	Corporate
	#1 Compounding Assort, Containment Isolation (CACI) Incident		CS Test	03/02/2017	Daily	Corporate
	#1 Compounding Assort, Containment Isolation (CACI) Incident		CS Test	03/07/2017	Daily	Corporate
	#1 Laminar Airflow Washdown (LAW) Wash Hood		CS Test	03/05/2017	Daily	Corporate
	#2 Sterile Repack Pump (SRP)		CS Test	03/04/2017	Daily	Corporate
	#2 Compounding Assort, Containment Isolation (CACI) Incident		CS Test	03/03/2017	Daily	Corporate
	#3 Compounding Assort, Containment Isolation (CACI) Incident		CS Test	02/22/2017	Daily	Corporate
	#3 Compounding Assort, Containment Isolation (CACI) Incident		CS Test	03/10/2017	Daily	Corporate



Reports Function

The screenshot shows the 'Reports' section of a software interface. On the left, there is a list of reports with columns for 'Report Title', 'Status', 'Last Run', and 'Next Run'. The reports include various compliance tasks like 'Pharmacy Compliance', 'Sterile Compounding', and 'Controlled Substance'. On the right, there are search and filter options for 'Task Compliance', 'Pharmacy Compliance', and 'Task Compliance'.

Reports Function

The screenshot displays a detailed view of a report task. The table below shows the task details and its history.

Title	Assigned To	Due	Frequency	Type	Completed	Attachment	Attachment Req.	Last Updated	Comments/Notes
Pharmacy Compliance	Jeffery	05/02/2014	Daily	Compliance	05/02/2014	-	-	Jeffery	Jeffery
Task Compliance	Jeffery	05/02/2014	Daily	Compliance	05/02/2014	-	-	Jeffery	Jeffery
Controlled Substance	Jeffery	05/02/2014	Weekly	Compliance	05/02/2014	-	-	Jeffery	Jeffery

Reports Function

• Raw Data Spreadsheet Sample

Title	Status	Frequency	Category	Due	Complete	Month	Site Category	Year
*PAM #1 Laminar Airflow Workbench (LAFW)	Completed On-Time	Daily	Sterile Compounding	3/14/2017	3/14/2017	March	Hospital	2017
Sterile inner gloves	Completed On-Time	Daily	Sterile Compounding	3/14/2017	3/14/2017	March	Hospital	2017
Perform Split Billing Automatic and Manual Accumulation Accuracy	Completed On-Time	Monthly	3408	3/16/2017	3/16/2017	March	Hospital	2017
Perform Split Billing Automatic and Manual Accumulation Accuracy	Completed On-Time	Monthly	3408	3/16/2017	3/16/2017	March	Hospital	2017
Verify all 3408 Audit Reports (Appendix 2-4) for previous month have been confirmed and sub	Completed On-Time	Monthly	3408	3/16/2017	3/16/2017	March	Hospital	2017
All courters, pass-through windows, work surfaces, sink areas are disinfected daily	Completed Late/incomplete	Weekdays	Sterile Compounding	3/2/2017	3/2/2017	March	Medical Group	2017
Pressure controls are recorded	Completed Late/incomplete	Weekdays	Sterile Compounding	3/2/2017	3/2/2017	March	Medical Group	2017
Compounding aseptic isolator (CAI)	Completed On-Time	Daily	Sterile Compounding	3/2/2017	3/2/2017	March	Hospital	2017
Chem Floor mopping performed from cleanest room (buffer) to less clean area (anteroom)	Completed On-Time	Weekdays	Sterile Compounding	3/2/2017	3/2/2017	March	Hospital	2017
Chem Pressure gauge/wall velocity meter	Completed On-Time	Weekdays	Sterile Compounding	3/2/2017	3/2/2017	March	Hospital	2017
PAM Laminar Airflow Workbench (LAFW)	Completed On-Time	Daily	Sterile Compounding	3/2/2017	3/2/2017	March	Hospital	2017
Reconciling Controlled Substance Vials Discrepancies in AutoDose-Rx	Completed On-Time	Weekdays	Controlled Substance Monitoring	3/2/2017	3/2/2017	March	Hospital	2017
Reconciling Manual Admins to the ADT	Completed On-Time	Weekdays	Controlled Substance Monitoring	3/2/2017	3/2/2017	March	Hospital	2017

