Ensuring HIPAA Compliance for Across-Institution Research Projects which Share PHI

Pierre-André La Chance

Mike Allison

Gary Ansell

Kaiser Permanente Center for Health Research





- Kaiser Permanente provides prepaid health care (including Medicaid and Medicare) to people living in the Portland/Vancouver metropolitan area, as well as the communities of Longview and Kelso, Washington, and Salem, Oregon.
- Enrollment in the medical program now stands at more than 475,000.
- Nationally, Kaiser Permanente provides prepaid health care to 8.7 million members

Advancing Knowledge to Improve Health

Kaiser Permanente The Center for Health Research

Three Sites-One Mission

Each TCHR site conducts professionally independent, public domain research and disseminates its findings in the scholarly literature and scientific community.

2007 Data (Mid-year)

	Northwest	Hawaii	Georgia	Total
Member Population	485,000	223,000	283,000	991,000
Researchers	69	38	21	127
Active Studies	302	27	62	391
Budget (2007)	29.7M	4.3M	2.0M	36.0M
Budget (2006)	26.9M	4.0M	1.7M	32.6M
Employees	231	72	19	322







- Disclosing PHI for research purposes differs from doing so for Payment, Treatment, and Operations
- Disclosures performed by research staff who do this infrequently and not as a major focus of their jobs
- What challenges does this present?





- How can we know what we don't know?
- How should we act on what we should know?
- How can we provide support for people needing to disclose PHI on a very irregular basis?
- How can we document all agreements?
- How do we document all communications?





- How can we stream-line paper-based systems to create a process that is more efficient and more accurate?
- How can we support a standardized nomenclature consistent across multiple departments and multiple players?
- How can we see train wrecks coming and prevent them ahead of time?

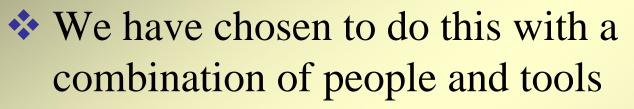




- And the two big issues...
 - How can we ensure compliance?
 - How can we survive an audit?







- A HIPAA Manager
- A HIPAA Coordinator
- Compliance Manager





- The HIPAA Manager (among other things) serves as our IT liaison to our Institutional Review Board (IRB)
- The HIPAA Coordinator serves as our day-to-day compliance connection to our research projects
- Compliance Manager is our integrated tracking system used enter baseline information, schedule and trigger compliance events, document communications, and archive agreements





Active Projects:

--My projects--

¥

Compliance Documents

 What is Protected Health

 Information?

 What you need before

 creating a DUA

General Documents 💌

Current Folder: 🔄 <u>General Documents</u>

Compliance Manager

ҍ Previous Folder

📁 New Folder 🔰 👌 Upload Files

<u>Name</u>	Title	<u>Posted</u>		Details
General Documents	Content Folder			
🔁 Minutes	Content Folder		<u>Edit</u>	<u>Delete</u>
PHI.pdf	What is Protected Health Information?	8/10/2007 4:00:13 PM	<u>Edit</u>	Delete more
🔁 Info needed from PM for DUA.pdf	What you need before creating a DUA	10/9/2007 12:31:44 PM	<u>Edit</u>	Delete more

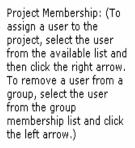


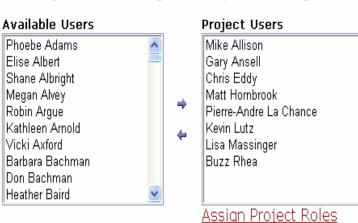
Administration - Project Management

Assign Project users:

Project Name:

Test Project 1 for working with Compliance Manager







User Management

Select a User to update or click on the new user button to add a new user.

Compliance Manager

Users:	Select User	~	<u>Add</u> <u>New</u>
Username:			
First Name:			
Last Name:			
Email:			
Enable auto email contact:			
Access Level:	User	~	
	Available	Assigned	
Application Roles:		÷	
Update	Remove	Cancel/GoBack	

Compliance Manager

<u>Details</u>

Details

10/22/2007 9:11 AM

Project Details

DUA5-TEST-PROJECT-01

DTA2-TEST-PROJECT-01

Project & RSPO #:	TEST-PROJECT-01					
Acronym:	TEST1					
Title:	Test Project 1 for working with Compliance Manager					
Description:	This a text case for ComplianceManag	jer				
PI:	Allison, Michael					
Co-PI(s):						
Main Contact/Project	Gary Ansell					
Manager:	,					
Project Start Date:	11/1/2007					
Additional Contact Info:	None of your business					
Current Status:	Initial agreement needs reviewed 7	/20/2007 12:07 PM				
Talla Ducines Infe	During the Discussion					
Edit Project Info	Project Discussion					
Agreements		Create New Agree	ment			
-	Obst.					
DUA/DTA	Status	Date	Details			
DUA1-TEST-PROJECT-01 DUA3-TEST-PROJECT-01	Agreement Uploaded	7/20/2007 12:15 PM	<u>Details</u> Dotails			
DUA3-TEST-PROJECT-01 DUA6-TEST-PROJECT-01	Anticipated date of agreement set Agreement Uploaded	10/29/2007 1:32 PM	<u>Details</u> Dotails			
DUA6-TEST-PROJECT-01 DUA4-TEST-PROJECT-01	Agreement uploaded Anticipated date of agreement set	10/9/2007 10:20 AM 10/29/2007 1:34 PM	<u>Details</u> <u>Details</u>			
DUA4-TEST-PROJECT-01	Anticipated date of agreement set	10/29/2007 1:34 PM	Decails			

Anticipated date of agreement set



TEST1

Test Project 1 for working with Compliance Manager

Click on the Topic title to read the the replies. Click on Add new Topic to add a new topic.

Add new topic | Back to Project

Topics (1)

Newest Oldest

This is a test (2 replies Last:10/10/2007 10:30:52 AM) Posted: Chris Eddy 10/10/2007 10:29:18 AM

this is a test of the bboard.



Project Details

IRB/RSPO #:	TEST-PROJECT-01	
Acronym:	TEST1	
Title:	Test Project 1 for working with Compliance Manager	*
Description:	This a text case for ComplianceManager	^
		~
PI:	Allison, Michael	
Original PI:		
Co-PI(s):		×
KP Sponsor:	COMPLIANCE	
Main Contact/Project Manager:	Gary Ansell	
Project Start Date:	11/1/2007	
IRB Activity Status: IRB Study Type:	Active Test ONLY	
Addtional Contact Info:	None of your business	^
De at Desiret		×
Past Project Acronyms:	None	~
Current Status:	Initial agreement needs reviewed 7/20/2007 12:07:20 PM	
Active:	Project is currently active	

Project has been reviewed by RIPS

Home | Contact RIPS | Administration

Manage Project Users

Review:

Edit Reason: Data Use Agreement	<u>B</u> Agreement is needed
ngroomone	Reasons: Contains Unlimited Data moving out of CHR Contains Limited Data moving out of CHR
Data Transfer Agreement	Agreement is needed
	Reasons: Contains Unlimited individual-level Data Contains Limited individual-level Data



Return to project

Agreement Details

Agreement ID:	DTA1-NW-02WVoll-08
IRB #:	NW-02WVoll-08
Project Acronym:	BOLD
Project Title:	Burden of Obstructive Lung Disease (BOLD) Phase II
Agreement Type:	Data Transfer Agreement
Agreement Version:	
Agreement Status:	Agreement completed
Agreement Status Date:	10/8/2007 9:16:15 AM
Reason for agreement:	Contains Limited individual-level Data After 10/1/07 discussion between Mike and Bill.
Anticipated date of implementation:	10/4/2007 Edit Date
Agreement Effective Date:	not set

Discuss Agreement

- View Current Agreement
- Create New Version
- Printable Version
- Manage Appendices

History of agreement versions

No historical versions of this data agreement have been created.



Data Recipients

							Add Recipient
Name	Address	Address2	City	State	Zipcode	Country	Fax
<mark>Select</mark> Center for Health Research/Hawaii	501 Alakawa	Suite 201	Honolulu	HI	96817	USA	(808) 432-4785
<mark>Select</mark> David K. Blough, PhD	891 Bear Ridge Drive NW		Issaquah	WA	98027	USA	
<mark>Select</mark> Group Health Center for Health Studies	1730 Minor Avenue		Seattle	WA	98101	USA	(206) 287-2826
Select Inc	133 Brookline Ave.	6th floor	Boston	МА	02215	USA	(617) 509-9859
<mark>Select</mark> Health Partners Research Foundation	8170 33rd Avenue South		Bloomington	MN	55425	USA	(952) 967-5022
<u>Select</u> Kaiser Permanente Center for Health Research	3800 N. Interstate Avenue		Portland	OR	97227	USA	(503) 335-2424
<u>Select</u> Kaiser Permanente Colorado	-	10350 E. Dakota Ave., 3rd Floor	Denver	со	80247	USA	(303) 344-7392
<u>Select</u> Kaiser Permanente Northern California	2000 Broadway, Floor 2		Oakland	CA	94612	USA	(510) 891-3508
<mark>Select</mark> Marshfield Clinic Research Foundation	1000 North Oak Avenue (1R3)		Marshfield	WI	54449	USA	
Select METRO	600 NE Grand Avenue		Portland	OR	97227	USA	(503) 797-1930
<mark>Select</mark> Oregon Health & Science University	3181 SW Sam Jackson Park Road		Portland	OR	97239	USA	
<u>Select</u> Patient Locator, Inc.	500 E. Broad Street - Suite 100	PO Box 511	Mansfield	ТΧ	76063- 0511	USA	(817) 473- 0113
<mark>Select</mark> The University at Alabama, Birmingham	1530 3rd Avenue S., AB 1170		Birmingham	AL	35294	USA	(205) 975-5977

Compliance Manager

Administration - Edit Email Templates

Select an email message template to edit	
AgreementCompleteAlert	
Email From Name:	
Email From Address:	
Subject	
Compliance Manager: All signatures have been completed for	r agre
Message	
The agreement found in the link below is now complete and has been signed by all required parties.	
Update Email Template	



Compliance Manager

Project List

Add Ne	w Project	RIPS Rev	General F view Status:	Project Status: Reviewed	Active	* *	Reset List
			To search phrase in	n for an exact n quotes (i.e. "m	ame or titl vy project t	itle")	
IRB #	Acronym	Title	<u>Status</u>	Status Date	Reviewed		arch
NW- 02WVoll- 08	BOLD	Burden of Obstructive Lung Disease (BOLD) Phase II	Initial agreement needs reviewed	10/2/2007 8:34:31 AM	Y		Agreements
NW- 02VStev- 02		Weight Loss Maintenance Trial (MAINTENANCE) - Coordinating Center	Initial agreement needs reviewed	8/30/2007 8:32:33 AM	Y	<u>Edit</u>	Agreements
NW- 04YMich- 01		Neighborhood Accessibility and Body Composition in Older Women	Initial agreement needs reviewed	11/5/2007 4:24:03 PM	Y	<u>Edit</u>	<u>Agreements</u>
NW- 04FLync- 03	Family Cost	Measurement of Family Costs of Child Mental Illness (Family Cost)	Initial agreement needs reviewed	10/4/2007 11:35:42 AM	Y	<u>Edit</u>	<u>Agreements</u>
NW- 06MRami- 01		HR-QOL in colorectal cancer survivors with stomas, minority supplement: "Women, Sexuality and Stomas".	Initial agreement needs reviewed	10/5/2007 2:20:40 PM	Y	<u>Edit</u>	<u>Agreements</u>
NW- 06MDaya- 01	ROC PRIMED	Resuscitation Outcomes Consortium: Prehospital Resuscitation using an Impedance Valve & Early vs. Delayed Analysis - (ROC PRIMED) Trial	Initial agreement needs reviewed	9/19/2007 9:08:38 AM	Y	<u>Edit</u>	<u>Agreements</u>
NW- 07ANale- 02	VSD	Vaccine Safety Datalink (VSD): Real-Time Safety Surveillance for the Early Detection of Adverse Events	Initial agreement needs reviewed	9/27/2007 5:08:31 PM	Y	<u>Edit</u>	<u>Agreements</u>
NW-		Vaccine Safety Datalink (VSD): Safety of TIV	Initial agreement	10/15/2007		- 0	

Administration – Announcements

Select an announcement to edit or delete.

Posted date

Edit/delete announcement :

Add an announcement:

<u>Title</u> <u>Posted by</u>

Expires date

Ready to Post

OnLine Edit Delete



Please feel free to contact me if you would like some additional information that might be useful as you build your compliance solutions.

> Pierre-André La Chance pierre.lachance@kpchr.org

