

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

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- ❖ 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



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?



- ❖ We have chosen to do this with a combination of people and tools
 - ❖ 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



Compliance Manager

To create or manage your data agreements, select one of the projects below. [Contact RIPS](#) if you cannot find the expected project (projects are listed by study acronym and IRB/RSPD number).

Active Projects:


--My projects--

Compliance Announcements

Add +

Compliance Documents

 [What is Protected Health Information?](#)

 [What you need before creating a DUA](#)







General Documents ▾

Current Folder:  [General Documents](#)

 [Previous Folder](#)

 [New Folder](#)

 [Upload Files](#)

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



Administration - Project Management

Assign Project users:

Project Name:

Test Project 1 for working with Compliance Manager

Project Membership: (To assign a user to the project, select the user from the available list and then click the right arrow. To remove a user from a group, select the user from the group membership list and click the left arrow.)

Available Users

Phoebe Adams
Elise Albert
Shane Albright
Megan Alvey
Robin Argue
Kathleen Arnold
Vicki Axford
Barbara Bachman
Don Bachman
Heather Baird



Project Users

Mike Allison
Gary Ansell
Chris Eddy
Matt Hornbrook
Pierre-Andre La Chance
Kevin Lutz
Lisa Massinger
Buzz Rhea

[Assign Project Roles](#)

[Back](#)

[Save](#)



User Management

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

Users:

[Add](#)
[New](#)

Username:

First Name:

Last Name:

Email:

**Enable auto
email contact:**

☒

Access Level:

Available

Assigned

**Application
Roles:**

[Update](#)[Remove](#)[Cancel/GoBack](#)



Project Details

Project & 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

Co-PI(s):

Main Contact/Project Manager: Gary Ansell

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

[Edit Project Info](#)[Project Discussion](#)

Agreements

[Create New Agreement](#)

| DUA/DTA | Status | Date | Details |
|----------------------|-----------------------------------|--------------------|-------------------------|
| DUA1-TEST-PROJECT-01 | Agreement Uploaded | 7/20/2007 12:15 PM | Details |
| DUA3-TEST-PROJECT-01 | Anticipated date of agreement set | 10/29/2007 1:32 PM | Details |
| DUA6-TEST-PROJECT-01 | Agreement Uploaded | 10/9/2007 10:20 AM | Details |
| DUA4-TEST-PROJECT-01 | Anticipated date of agreement set | 10/29/2007 1:34 PM | Details |
| DUA5-TEST-PROJECT-01 | | | Details |
| DTA2-TEST-PROJECT-01 | Anticipated date of agreement set | 10/22/2007 9:11 AM | Details |



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: | Active |
| IRB Study Type: | Test ONLY |
| Additional Contact Info: | None of your business |
| Past Project Acronyms: | None |
| Current Status: | Initial agreement needs reviewed 7/20/2007 12:07:20 PM |
| Active: | <input checked="" type="checkbox"/> Project is currently active |
| Review: | <input type="checkbox"/> Project has been reviewed by RIPS |

[Manage Project Users](#)

| | |
|------------------------------|--|
| Edit Reasons | |
| Data Use Agreement | Agreement is needed |
| 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 |
|------------------------|--|---------------------------------|---------------------------------|-------------|-------|------------|---------|-----------------|
| Select | Center for Health Research/Hawaii | 501 Alakawa | Suite 201 | Honolulu | HI | 96817 | USA | (808) 432-4785 |
| Select | David K. Blough, PhD | 891 Bear Ridge Drive NW | | Issaquah | WA | 98027 | USA | |
| Select | Group Health Center for Health Studies | 1730 Minor Avenue | Suite 1600 | Seattle | WA | 98101 | USA | (206) 287-2826 |
| Select | Harvard Pilgrim Health Care, Inc | 133 Brookline Ave. | 6th floor | Boston | MA | 02215 | USA | (617) 509-9859 |
| Select | Health Partners Research Foundation | 8170 33rd Avenue South | | Bloomington | MN | 55425 | USA | (952) 967-5022 |
| Select | Kaiser Permanente Center for Health Research | 3800 N. Interstate Avenue | | Portland | OR | 97227 | USA | (503) 335-2424 |
| Select | Kaiser Permanente Colorado | Regional Office | 10350 E. Dakota Ave., 3rd Floor | Denver | CO | 80247 | USA | (303) 344-7392 |
| Select | Kaiser Permanente Northern California | 2000 Broadway, Floor 2 | | Oakland | CA | 94612 | USA | (510) 891-3508 |
| Select | 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 |
| Select | Oregon Health & Science University | 3181 SW Sam Jackson Park Road | | Portland | OR | 97239 | USA | |
| Select | Patient Locator, Inc. | 500 E. Broad Street - Suite 100 | PO Box 511 | Mansfield | TX | 76063-0511 | USA | (817) 473- 0113 |
| Select | The University at Alabama, Birmingham | 1530 3rd Avenue S., AB 1170 | | Birmingham | AL | 35294 | USA | (205) 975-5977 |



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 agre

Message

The agreement found in the link below is now complete and has been signed by all required parties.

Update Email Template



Project List

[Add New Project](#)

General Project Status: Active
[Reset List](#)

RIPS Review Status: Reviewed

To search for an exact name or title, surround the phrase in quotes (i.e. "my project title")

 [Search](#)

| IRB # | Acronym | Title | Status | Status Date | Reviewed | | |
|---------------|-------------|---|----------------------------------|-----------------------|----------|----------------------|----------------------------|
| NW-02WVoll-08 | BOLD | Burden of Obstructive Lung Disease (BOLD) Phase II | Initial agreement needs reviewed | 10/2/2007 8:34:31 AM | Y | Edit | Agreements |
| NW-02VStev-02 | | Weight Loss Maintenance Trial (MAINTENANCE) - Coordinating Center | Initial agreement needs reviewed | 8/30/2007 8:32:33 AM | Y | Edit | Agreements |
| NW-04YMich-01 | | Neighborhood Accessibility and Body Composition in Older Women | Initial agreement needs reviewed | 11/5/2007 4:24:03 PM | Y | Edit | Agreements |
| 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 | Edit | Agreements |
| 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 | Edit | Agreements |
| 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 | Edit | Agreements |
| 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 | Edit | Agreements |
| NW-07ANale-02 | | Vaccine Safety Datalink (VSD): Safety of TIV | Initial agreement | 10/15/2007 | | | |



Administration – Announcements

Select an announcement to edit or delete.

Edit/delete announcement :

Add an announcement:

| <u>Title</u> | <u>Posted by</u> | <u>Posted date</u> | <u>Expires date</u> | 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.

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