Multi-Site Research Compliance Issues

HCCA Research Compliance Conference
June 4, 2013
Austin, TX

Major Topics

• Compliance Plans For Multi-Site Research
• Compliance Coordination Among Sites
• IRB & Other Approvals And Jurisdiction
• Privacy Issues In Exchanging Information
Some Issues In Compliance Plans

- Contract Logistics & Trends
  - Usual Stuff
  - Stark/Anti-Kickback/False-Claims
- PI Compliance

Contracting Logistics And Trends
Typical Types Of Contracts

• Clinical Trial Agreement
  – 2-way
  – 3-way
• Principal Investigator Agreement
• Sub-investigator Agreement
• Hospital/Facility Services Agreement For Clinical Research
• Facility Letter/Agreement (“Formerly Letter Of Indemnification”)

Clinical Trial Agreement (CTA)

• Main Agreement Between Sponsor And Research Institution
  – Institution Could Be Hospital Or Independent Physician/Site
• Establishes Research Institution As Responsible For Conduct Of Study
• Indemnifies Research Institution
• Establishes Payment Terms To Institution
• Sponsors Have Their Own Templates
  – Some “Master Agreements”
2 Way Vs. 3+ Way CTA

• 2 Way
  – Between The Sponsor And The Research Institution Only

• 3+ Way
  – Between Sponsor, Research Institution And One Or More Third Party(ies).
  – Usually Cumbersomely And Incorrectly Written For All Parties
  – Resultantly Takes Longer Time To Negotiate

Investigator Agreements

• Used When Hospital/Institution Pays An Independent Physician
  – Principal Investigator Agreement (More Detailed)
  – Sub-investigator Agreement

• Single Use Agreements Vs Master Agreement/Work Orders

• Usual “Non-Research” Rules Apply
  – Stark, Anti-kickback, FMV Parameters Etc.
Hospital/Facility Services Agreement For Clinical Research

- Used When Physician/Institution Pays Hospital OR Other Facility Subcontractor
- Single Use Agreements Vs Master Agreement/Work Orders

Facility Agreement (Formerly “Letter Of Indemnification”)

- Usually Used When There Is A 2-Way CTA Between A PI/Institution And A Sponsor Not Involving The Facility
- Usually Provides For Indemnification To Hospital/Facility
- Sometimes Binds Hospital/Facility To Other Things
  - Confidentiality Of Protocol
  - Intellectual Property Rights Of Sponsor’s Investigational Products
- Sponsors Have Their Own Templates
Hospital As Research Institution

Clinical Trial Agreement

PI Agreement (if not employed)

Sub-I Agreements (if not employed)

Hospital As Research Institution: (2-way CTA)

Clinical Trial Agreement

Facility Agreement (a.k.a. Indemnification Letter)

Clinical Trial Agreement

Hospital Services Agreement For Clinical Research
Independent Entity As Research Institution:
(3-way CTA)

Double Billing Danger (Obvious)
Double Billing Danger (Not So Obvious)

“It’s all standard of care.”

What CMS Will See When NCD Number Is Placed On Bill: Inconsistent Research Billing Across Country

- SITE #1: Billed for X, Y & Z
- SITE #2: Didn’t Bill For X, Y & Z
- SITE #3: Billed for X, Y & Z
- SITE #4: Billed For X & Y but not Z
- SITE #5: Didn’t Bill For X, Y & Z

NCT Number

• Creates opportunities for CMS to audit sites for recovery of funds
**Where’d The Line Items Go?**

<table>
<thead>
<tr>
<th></th>
<th>Visit 1</th>
<th>Visit 2</th>
<th>Visit 3</th>
<th>Visit 4</th>
</tr>
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<tbody>
<tr>
<td>Informed Consent</td>
<td>$150</td>
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<td>Medical History</td>
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<tr>
<td>Physical Exam</td>
<td>SOC</td>
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<td>ECG</td>
<td>SOC</td>
<td>$75</td>
<td>$75</td>
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<tr>
<td>Lab</td>
<td>SOC</td>
<td>SOC</td>
<td>$30</td>
<td>SOC</td>
</tr>
<tr>
<td>Pharmacy Dispensing Fee</td>
<td>$30</td>
<td></td>
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<tr>
<td>Principal Investigator Fee</td>
<td>$175</td>
<td>$175</td>
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<td>$175</td>
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<tr>
<td>Study Coordinator Fee</td>
<td>$175</td>
<td>$175</td>
<td>$175</td>
<td>$175</td>
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<tr>
<td>Overhead</td>
<td>$228</td>
<td>$159</td>
<td>$159</td>
<td>$175</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$878</strong></td>
<td><strong>$614</strong></td>
<td><strong>$614</strong></td>
<td><strong>$675</strong></td>
</tr>
</tbody>
</table>

**Vs**

<table>
<thead>
<tr>
<th></th>
<th>Visit 1</th>
<th>Visit 2</th>
<th>Visit 3</th>
<th>Visit 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate</td>
<td>$878</td>
<td>$614</td>
<td>$614</td>
<td>$675</td>
</tr>
</tbody>
</table>

**When The Government “Line Items” It Out, Who Will They Believe?**

Sponsor Payment $878

- “All study procedures”

Federal Payment $200

- “Some Procedures”
  - Deep Thoughts
  - Great Reputation
  - Ultimate responsibility

Sponsor Payment $878

- “Some Procedures”
- “Extra for My...”
Anti-kickback Violation For Non-employed Physicians And IRB Fees?

Does your insurance even cover this as a function to support the hospital? Or do they consider this your being a "commercial IRB?"

PI And Research Conduct Compliance
From Institution Perspective...

• Failure-Mode-Effects- & Criticality-Analysis (FMECA) Would Result In Things Like:
  – PI Not Properly Consenting Subjects That Receive Hospital Services
    • Kus V. Sherman Hospital, 268 Ill.App.3d 771 (1995)
  – Protocol Deviations
    • Intentional Or Unintentional
    • Hospitals Must Follow Physician Orders, Not Protocols.

Other Common FMECA Findings

• Failure To Follow The Rules
  – Research Related (E.G. OHRP, FDA)
    • I.E. Not Reporting Aes
    • I.E. Not Following Irbs
  – Non-Research Related
    • Joint Commission Accreditation Standards
      – Copy Of Informed Consent Not On Patient Chart
      – Pharmacy Not “Controlling” Investigational Drugs
    • Medicare (Conditions Of Participation, Etc)
      – Copy Of informed Consent Not On Patient Chart
    • Institution’s Code Of Conduct
    • “Double-billing”
Institution’s Liability For Informed Consent???

• For Treatment
  – Courts Consistent It Is Physician’s Obligation
• For Clinical Trials However…
  – Institutions Have Been Held Liable When PI Did Not Properly Consent Subjects
    • Kus V. Sherman Hospital, 268 Ill.App.3d 771 (1995)
    • Iolab Case (PA)

Credentialing/Privileging Philosophies

Certified Physician Investigators (CPI) are “Deemed” To meet the requirements by HCPro’s Privileging Practice Category #415: Clinical Investigator
Credential/Privileging: Confirmation Of Training

• Demonstrate Receipt Of Human Research Protection And ICH-GCP Training
  – Determine Training Threshold
  – Prescriptive Versus Goal-oriented Criteria
    • Prescriptive
      – “All PIs Must Complete Our CITI Course.”
      – “All PIs Must Be CPI Certified Or Working Towards Certification”
    • Goal-oriented: “All PIs Must Have CPI Certification Verified Online Or Submit Their Training Certificates In HPR/GCP For Peer Review Of Adequacy”.
    • Acceptance Of Other Institutional Trainings.

Not All “Certifications” Are Alike

<table>
<thead>
<tr>
<th>Possession of “Certificate”</th>
<th>Professional “Certification” (Non-Accredited Programs/Vendors)</th>
<th>Professional “Certification” (Accredited by NCCA/ISO)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Just About Anybody</td>
<td>Society of Clinical Research Associates</td>
<td>Association/Academy of Clinical Research Professionals (ACRP)/Academy of Physicians in Clinical Research (APCR)</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.socra.org">www.socra.org</a></td>
<td><a href="http://www.acrpmnet.org">www.acrpmnet.org</a></td>
</tr>
<tr>
<td></td>
<td>• CCRP (Clinical Research Professionals)</td>
<td>• CPI (Certified Physician Investigator)</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.acrpmnet.org">www.acrpmnet.org</a></td>
<td>• CCRC (Certified Clinical Research Coordinator)</td>
</tr>
<tr>
<td></td>
<td>• CCTI (Certified Clinical Trials Investigator)</td>
<td>• CCRA (Certified Clinical Research Associate)</td>
</tr>
<tr>
<td></td>
<td>Others For “Indirect” Research Staff</td>
<td></td>
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<tr>
<td></td>
<td>• CCIP’s CPI (Certified IRB Professional)</td>
<td></td>
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<tr>
<td></td>
<td>• HCCA’s CHRA (Certified in Healthcare Research Compliance)</td>
<td></td>
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<td></td>
<td>• MAGI’s CRCP (Certified Research Contract Professional)</td>
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<td></td>
<td>• NAIV’s CIM (Certified IRB Manager)</td>
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<tr>
<td></td>
<td>• RACC’s CRA (Certified Research Administrator)</td>
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<td></td>
<td>• RACC’s CPRA (Certified Pre-Award Research Administrator)</td>
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<tr>
<td></td>
<td>• RAPS’s RAC (Regulatory Affairs Certification)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• SCRM’s CCDM (Certified Clinical Data Manager)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• SQAP’s RQAP (Registered Quality Assurance Professional)</td>
<td></td>
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</table>
Jean-marc C. Haeusler Article
“Certification in Good Clinical Practice and Clinical Trial Quality: A Retrospective Analysis of Protocol Adherence in Four Multicenter Trials in the USA”

David M. Vulcano Article
“CPI™ Certification as Predictor of Clinical Investigators’ Regulatory Compliance”
Http://Dij.Sagepub.Com/Content/46/1/84.Abstract

<table>
<thead>
<tr>
<th>Hypothesis</th>
<th>Results</th>
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<tr>
<td>CPI™ certified investigators are predicted to earn the most favorable FDA audit result (NAI) over non-certified investigators.</td>
<td>Significant ($\chi^2 = 7.719$, $p = 0.005$).</td>
</tr>
<tr>
<td>CPI™ certified investigators are predicted not to earn the least favorable FDA audit result (OAI) over non-certified investigators.</td>
<td>Significant ($\chi^2 = 10.371$, $p = 0.001$).</td>
</tr>
</tbody>
</table>
Some Issues In Compliance Coordination

- IRB vs Administrative Approval
- Consistency of Study Documents
- Integration Issues in “Pay For Performance” Realities

IRB Approval/Oversight VS. Administrative Approval/Oversight

- What IRB Approval/Oversight Alone Is NOT ...

- IRB Approval/Oversight Alone = ☠️
- Administrative Approval/Oversight Alone (When IRB Review Is Also Required To Be Certified) = ☠️

- IRB Approval/Oversight (When Required) + Administrative Approval/Oversight = ☠️
Some General “Non-IRB” Oversight Responsibilities

- Feasibility
  - Costs (I.E. Staff, Supplies)
  - Reimbursements
    - Medicare Coverage Analysis
    - From Patient/Insurance
    - From Research Grant
  - Business Interrupts

- Certifying IRB Review

- Contracting
  - With Sponsors
  - With Independent Physicians
  - With Research Sites

- Individual Patient Reconciliation
  - Research Engaged In
  - Research Not Engaged In
  - Emergency Use of Test Article
  - Humanitarian use Devices
  - “Second Institution”
  - Treatment of Research-Related Injury

- Billing
  - Cost Distribution/Splitting Bills
  - Coding (Medicare) Bills

- Informed Consent
  - On Medical Charts- When/how
  - Core Measure Exclusion

Problematic Inconsistency Between Study Documents

Who Pays For Injury?- Informed Consent Language

COMPENSATION FOR INJURY

If you become ill or are hurt while you are in the study, get the medical care that you need right away.

If you are injured as a direct result of being part of this study, the study doctor will provide usual medical care. If this occurs, you will not have to pay medical expenses beyond those normally covered by your insurance. No additional financial help will be given.

Who Pays For Injury?- Clinical Trial Agreement Language

prescribed. The obligations under this Article S shall not apply to the extent that any such

(4) the Study subject’s failure to comply with instructions contained in the
Informed Consent executed by such subject or communicated to the subject by
Study personnel.
Examples Of Common Inconsistencies

CTA

Payment for Injury
Payment for Usual Care
Secondary Use of Specimens

Consent Form

Core Measure Requirements

Patient Presents With Specific Condition

Intervention 2

Intervention 3

Intervention 4

Clinical Trial Procedure 1

Clinical Trial Procedure 2

Clinical Trial Procedure 3

Good Report Card / Full Reimbursement

Unjustified Deviation

Bad Report Card / Decreased Reimbursement
To select “Yes” to this data element, BOTH of the following must be true:

1. There must be a signed consent form for clinical trial; and

2. There must be documentation on the signed consent form that during the stay the patient was enrolled in a clinical trial in which patients with the same condition as the measure set being studied.
Must Check “No” If...

1. Signed consent form is for an **observational** (non-experimental) study (e.g. registries).

2. It is not clear whether the study described in the consent form is experimental or observational.

3. It is not clear which study population the clinical trial is enrolling.

From HospitalCompare.HHS.gov

Heart Attack Patients Given ACE Inhibitor or ARB for Left Ventricular Systolic Dysfunction (LVSD)

**Why is this important?**

- Hospital 1: 100.0%
- Hospital 2: 99.0%
- Medical Center 1: 100.0%
- Medical Center 2: 98.0%
- Average for all reporting hospitals in Ten...: 99.0%
- Average for all reporting hospitals in The...: 97.0%
What CMS Will See When NCD Number Is Placed On Bill:
Inconsistent Inclusion Of Research Subjects In Quality
Measure Reporting

<table>
<thead>
<tr>
<th>Provider</th>
<th>Reason for False Elevation of Core Measure Stat</th>
<th>Correct Stat</th>
<th>Incorrect Stat</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td>False inclusion of 3 cases that followed the pathway when should have been excluded from denominator</td>
<td>20/25 = 80%</td>
<td>23/28 = 82%</td>
</tr>
<tr>
<td>#2</td>
<td>False exclusion of 3 cases that did not follow the pathway when they should have been included</td>
<td>25/30 = 83%</td>
<td>25/27 = 93%</td>
</tr>
</tbody>
</table>

Some Issues In IRB and Other Oversight

- IRB Coordination
- Conflict of Interest Coordination
Research Laws

IRB Approval/Oversight

• 45CFR46 (A.K.A. “Common Rule”)
• IRB Approval/Oversight Required When The Institution Is “Engaged” In “Research With Human Subjects”
• Human Subject Means A Living Individual About Whom An Investigator (Whether Professional Or Student) Conducting Research Obtains
  – Data Through Intervention Or Interaction With The Individual, Or
  – Identifiable Private Information

Research Laws

Exempt From IRB/Research Consent

• 45cfr46.101(b)(4) “Research Involving The Collection Or Study Of Existing Data, Documents, Records, Pathological Specimens, Or Diagnostic Specimens, If These Sources Are Publicly Available Or If The Information Is Recorded By The Investigator In Such A Manner That Subjects Cannot Be Identified, Directly Or Through Identifiers Linked To The Subjects.”
Summary Of Key Questions (And Aids) For Determining IRB Oversight

• Is It Research With Human Subjects?

• Is It Exempt?
  – 45CFR46.101(b)

• Are We Engaged In The Research?

Biggest Risk: Well Intentioned People Who Don’t Know What They Don’t Know

The Dunning–kruger Effect

• A Cognitive Bias In Which Unskilled People Make Poor Decisions And Reach Erroneous Conclusions, But Their Incompetence Denies Them The Metacognitive Ability To Recognize Their Mistakes.

• The Unskilled Therefore Suffer From Illusory Superiority, Rating Their Ability As Above Average, Much Higher Than It Actually Is.
**Biggest Compliance Risk With Local IRBs**

- Usually Well Intentioned People
- Often Not “Primary Job” Due To Volume
- Resources Diverted To Other “Fires”
- “My Manager Has No Idea What's Involved”
- “Self-audits” Diluted By Lack Of Knowledge
- Relying On More Friendly Audit Years Ago

**Common Problem Outsourcing To Irbs**

- **Human Subject Protection**
  - Risk/Benefit
  - Informed Consent
  - Local Context

- **Operational Review**
  - Feasibility Analysis
  - Contracts/Budgets
  - Internal Training
  - Operational Planning
  - Recognition of Subjects
  - Billing/Coding Prep

- Human Subject Protection
  - Risk/Benefit
  - Informed Consent

- Operational Review
  - Feasibility Analysis
  - Contracts/Budgets
  - Internal Training
  - Operational Planning
  - Recognition of Subjects
  - Billing/Coding Prep
Institutions Needing To Certify IRB Review

A systematic investigation designed to contribute to generalizable knowledge.

Research

With Human Subjects

Subject To Applicable Regulation

Non-Exempt

• OHRP Criteria
• FDA Criteria

Exempt

• OHRP Guidance on “Engaged”

Not Subject To Applicable Regulation

Non-Engaged Institutions

Not With Human Subjects

Engaged Institutions

Research involves obtaining information about living individuals through intervention or interaction with the individuals.

Research Laws

OHRP - Guidance On Engagement Of Institutions In Human Subjects Research

Relevant Examples From The Guidance On BEING Engaged ....

• Example #1: Institutions That Receive An Award Through A Grant, Contract, Or Cooperative Agreement Directly From HHS For The Non-Exempt Human Subjects Research
• Example #4: Employees Or Agents Interact For Research Purposes With Any Human Subject Of The Research.
• Example #5: Employees Or Agents Obtain The Informed Consent Of Human Subjects For The Research
• Example #6: Employees Or Agents Obtain For Research Purposes Identifiable Private Information Or Identifiable Biological Specimens From Any Source For The Research.
Research Laws

OHRP - Guidance On Engagement Of Institutions In Human Subjects Research

Relevant Examples From The Guidance On NOT Being Engaged:

- **Example #6:** “Institutions Whose Employees Or Agents Release To Investigators At Another Institution Identifiable Private Information Or Identifiable Biological Specimens Pertaining To The Subjects Of The Research.”
- **Example #7:** “Institutions Whose Employees Or Agents (A) Obtain Coded Private Information... And (B) Are Unable To Readily Ascertain The Identity Of The Subjects....”
- **Example #8:** Institutions Whose Employees Or Agents Access Or Utilize Individually Identifiable Private Information Only While Visiting An Institution That Is Engaged In The Research, Provided Their Research Activities Are Overseen By The Irb Of The Institution That Is Engaged In The Research.
- **Example #9:** “Institutions Whose Employees Or Agents Access Or Review Identifiable Private Information For Purposes Of Study Auditing (E.G. A Government Agency Or Private Company Will Have Access To Individually Identifiable Study Data For Auditing Purposes).”
- **Example #10:** “Institutions Whose Employees Or Agents Receive Identifiable Private Information For Purposes Of Satisfying U.S. Food And Drug Administration Reporting Requirements.”

Conflict Of Interest

- Responsibility Of Applicants For Promoting Objectivity In Research For Which PHS Funding Is Sought (42 C.F.R. Part 50, Subpart F)
- Responsible Prospective Contractors (45 C.F.R. Part 94)
- Other Branches Of Government Have Their Own (i.e. FDA @ 21CFR54)
PHS Requirements Of Awardee Institution

- The Policy Must Be Written And Available On A Public Website
- Investigators Must Be Informed Of The Policy
- Investigators Must Be Trained Prior To Engaging In PHS Funded Research And Every 4 Years Afterward Unless...
  - Policies Change
  - Investigator Is New To Institution (I.E. No Grandfathering Other Programs)
  - Investigator Was Found Non-compliant With The Policy

Requirements Of Sub-Recipients

- Option 1
  - Maintain Their Own Policies/Training In Compliance
  - Certify In A Contract That Theirs Is Compliant With New Regulations
- Option 2
  - Be Subject To Awardee Institution’s Policies
    - Pros: Eliminate Cost/Effort Of Developing Own
    - Cons: Loss Of Institutional/Investigator Privacy, Non-local Context/Demands
Some Issues In Exchange Of Information

- Research Regulations
- Privacy Regulations
- Business and Ethics Considerations

3 Independent But Related Decision Trees

- Research Laws
- HIPAA Compliance
- Business/Ethics Considerations
• Addresses (Among Other Things) What Is “Identifiable” When Re-identification Codes Are Needed By The Investigator

• 2 Required Conditions For A “Reidentification” Code To Be “Not Identifiable”

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Condition #1

• “The Private Information Or Specimens Were Not Collected Specifically For The Currently Proposed Research Project Through An Interaction Or Intervention With Living Individuals; And...”
Condition #2

“The Investigator(s) Cannot Readily Ascertain The Identity Of The Individual(s) To Whom The Coded Private Information Or Specimens Pertain Because, For Example:

- The Investigators And The Holder Of The Key Enter Into An Agreement Prohibiting The Release Of The Key To The Investigators Under Any Circumstances, Until The Individuals Are Deceased;
- There Are Irb-approved Written Policies And Operating Procedures For A Repository Or Data Management Center That Prohibit The Release Of The Key To The Investigators Under Any Circumstances, Until The Individuals Are Deceased; Or
- There Are Other Legal Requirements Prohibiting The Release Of The Key To The Investigators, Until The Individuals Are Deceased.”

### Key Differences Between Privacy Aspects Of OHRP And HIPAA

<table>
<thead>
<tr>
<th>OHRP</th>
<th>HIPAA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protects all research subjects privacy (identity of patients, providers, employees, visitors etc.)</td>
<td>Protects PHI Only</td>
</tr>
<tr>
<td>Less prescriptive on what is “de-identified”</td>
<td>Very prescriptive on what is “De-identified”</td>
</tr>
<tr>
<td>Waiver criteria for research consent only.</td>
<td>Waiver criteria for HIPAA authorization to disclose PHI only, not research consent.</td>
</tr>
</tbody>
</table>
Key Differences (Cntd)

HIPAA Compliance

- Research Consent As Ethical Issue
- Privacy as Legal and Ethical Issue

Research With Human Subjects

- Not Exempt
- Exempt (OHRP)

Decision #1

- Research Consent As Ethical Issue
- Privacy as Legal and Ethical Issue

Decision #2

Business Associate Agreements In Research

- In Most Cases, Not Applicable.
- BAAs Are Used When A Third Party Does A “Covered Function” On Behalf Of A “Covered Entity”.
- Per HIPAA Preamble On BAAs: “Research Is Not A Covered Function Or Activity”
- Creating De-identified Datasets And Limited Data Sets Can Be Done Under BAAs
Covered Entity (CE) contracts with Research Institution (RI) as Business Associate to access PHI to create datasets for CE’s use.

CE authorizes RI to create and scrub a dataset for CE’s use for a particular protocol. At this stage, RI cannot use any data for research purposes.

CE obtains scrubbed dataset from RI and RI’s access to PHI is terminated. CE determines if dataset is either de-identified or "Limited Data Set" as defined by HIPAA (i.e. eliminating all "safe harbor" PHI fields). If not, it is treated as PHI.

If provided via Individual Authorization, an Accounting of Disclosure (AOD) is not required by HIPAA. CE provides PHI to RI under normal policy.

If provided under IRB Waiver of Authorization, CE provides PHI to RI and for each Protocol...

PHI

Limited Data Set

De-Identified Data

1. With Authorization
2. Without Authorization
3. Via IRB/Privacy Board Waiver
4. Via Preparatory to Research
5. Via Research on Decedents
6. Allows some safe harbor fields in exchange for certain conditions being met in a "Data Use Agreement"
7. Safe Harbor Method
8. Statistical Certification Method

CE authorizes RI to create and scrub a dataset for CE’s use for a particular protocol. At this stage, RI cannot use any data for research purposes.

If provided under IRB Waiver of Authorization, CE provides PHI to RI and for each Protocol...

1 Note, RI (instead of CE) can obtain research consent/authorization only with IRB and CE approval.

1 Note, these are usually IRB exempt only if they are retrospective.

For each Protocol, if PHI is needed by RI, release requires either Individual Authorization (usually combined with research consent form) from patient by a member of CE’s workforce or copy of IRB Waiver of Authorization from IRB.

<50 Records accessed, AOD must be documented in usual way required by HIPAA

If >= 50 records accessed, can use “abbreviated” AOD method

8 Basic Categories Of Releasing Data For Research Under HIPAA

HIPAA Compliance
HIPAA Compliance

De-identified Data

• Not Subject To Accounting Of Disclosure
• No Contract Necessary (For HIPAA Purposes)
• How Do We Know It Is De-identified?
  – Certified By A Statistician That Risks Of Re-identification Is Very Small*; Or
  – Eliminating Certain Fields Listed In The Regulations (E.G. Safe Harbor Provision)

HIPAA Compliance

Two Options For HIPAA Deidentification

Option 1: “Safe Harbor”

• Eliminate Certain Fields Designated by HIPAA
• No actual knowledge that remaining information could be used alone or in combination with other information to re-identify.

Option 2: “Statistician Certification”

• Certified by a statistician as “very small* risk of re-identification” alone or in combination with other reasonably available information.
• Must keep documentation of method/results for >6 years.

* “very small” is not defined in regulation but note that de-identification safe harbor is studied to be at .04% reidentifiable.
**“Safe Harbor” Fields To Be Removed**

**1) Names.**

**2) All Geographic Subdivisions Smaller Than A State**, including Street Address, City, County, Precinct, Zip Code, and their equivalent geographical codes, **Except For The Initial Three Digits Of A Zip Code** if, according to the current publicly available data from The Bureau Of The Census:

   a. The Geographic Unit Formed By Combining All Zip Codes With The Same Three Initial Digits Contains More Than 20,000 People.
   b. The Initial Three Digits Of A Zip Code For All Such Geographic Units Containing 20,000 Or Fewer People Are Changed To 000.

**3) All Elements Of Dates (Except Year) For Dates Directly Related To An Individual**, including Birth Date, Admission Date, Discharge Date, Date Of Death; And **All Ages Over 89 And All Elements Of Dates (Including Year) Indicative Of Such Age**, except that such ages and elements may be aggregated into a single category of age 90 or older.

**4) Telephone numbers.**

**5) Facsimile numbers.**

**6) Electronic mail addresses.**

**7) Social security numbers.**

**8) Medical record numbers.**

**9) Health plan beneficiary numbers.**

**10) Account Numbers**

**11) Certificate/license numbers.**

**12) Vehicle identifiers and serial numbers**, including license plate numbers.

**13) Device identifiers and serial numbers.**

**14) Web universal resource locators (URLs).**

**15) Internet protocol (IP) address numbers.**

**16) Biometric identifiers, including fingerprints and voiceprints.**

**17) Full-face photographic images and any comparable images.**
“Safe Harbor” Fields To Be Removed

18) Any other unique identifying number, characteristic, or code **however** a covered entity may assign to, and retain with the health information a code or other means of record identification if that code is **not derived from or related to the information about the individual** (i.e. Initials) and **could not be translated to identify the individual**. The covered entity **may not use or disclose the code or other means of record identification for any other purpose** and may not disclose its method of re-identifying the information.

---

**Hint #1: Calculating LOS**

- **Date of Admit:** 11/17/2012
- **Date of Discharge:** 11/25/2012
- **Year of Admit:** 2012
- **Length Of Stay:** 8
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Hint #2: Use Relative Dates

Year of Admit: 2012
Day of Diagnosis: -1
Day of Infection: 2
LOS: 5
Days to Readmission: 7

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Hint #3: Strategies For Age Over 89

<table>
<thead>
<tr>
<th>Age</th>
<th>Age</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>60</td>
<td>60</td>
<td>60</td>
</tr>
<tr>
<td>76</td>
<td>76</td>
<td>76</td>
</tr>
<tr>
<td>75</td>
<td>75</td>
<td>75</td>
</tr>
<tr>
<td>82</td>
<td>82</td>
<td>82</td>
</tr>
<tr>
<td>88</td>
<td>88</td>
<td>&gt;89</td>
</tr>
<tr>
<td>86</td>
<td>86</td>
<td>88</td>
</tr>
<tr>
<td>79</td>
<td>79</td>
<td>86</td>
</tr>
<tr>
<td>77</td>
<td>77</td>
<td>79</td>
</tr>
<tr>
<td>75</td>
<td>75</td>
<td>77</td>
</tr>
</tbody>
</table>
**HIPAA Compliance**

**Limited Data Set**

- Allows For Some Excluded “Safe Harbor” Fields
- Requires “Data Use Agreement”
  - Regulated Requirements By HIPAA In Agreement

<table>
<thead>
<tr>
<th></th>
<th>De-Identified</th>
<th>Limited Data Set</th>
</tr>
</thead>
<tbody>
<tr>
<td>Geography</td>
<td>Forbids All Smaller then State</td>
<td>Forbids Postal Address other than town,city or state</td>
</tr>
<tr>
<td>Zip Code</td>
<td>First 3 Digits only, with “000” if N&lt;20,000</td>
<td>Allows</td>
</tr>
<tr>
<td>Date (e.g. Birth, Death, Admit Discharge etc)</td>
<td>Year Only</td>
<td>Allows Full Date</td>
</tr>
<tr>
<td>Age</td>
<td>OK but none over 89 (i.e. “90+” only)</td>
<td>Allows</td>
</tr>
</tbody>
</table>

**HIPAA Compliance**

**Data Use Agreement Requirements**

- **Specific Permitted Uses And Disclosures** Of The Limited Data Set By The Recipient Consistent With The Purpose For Which It Was Disclosed (A Data Use Agreement Cannot Authorize The Recipient To Use Or Further Disclose The Information In A Way That, If Done By The Covered Entity, Would Violate The Privacy Rule).
- Identify **Who Is Permitted To Use Or Receive The Limited Data Set**.
- Stipulations That The Recipient Will
  - **Not Use Or Disclose The Information Other Than Permitted** By The Agreement Or Otherwise Required By Law.
  - **Use Appropriate Safeguards** To Prevent The Use Or Disclosure Of The Information, Except As Provided For In The Agreement, And **Require The Recipient To Report To The Covered Entity Any Uses Or Disclosures In Violation Of The Agreement** Of Which The Recipient Becomes Aware.
  - **Hold Any Agent Of The Recipient (Including Subcontractors) To The Standards, Restrictions, And Conditions Stated In The Data Use Agreement With Respect To The Information**.
  - **Not Identify The Information Or Contact The Individuals**.
**HIPAA Compliance**

**Caution: Free Text Fields**

<table>
<thead>
<tr>
<th>Age</th>
<th>State</th>
<th>Symptom</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>45</td>
<td>Tennessee</td>
<td>Depression</td>
<td>Talked to James Johnson (husband) about pt’s suicide attempt.</td>
</tr>
<tr>
<td>&gt;89</td>
<td>Washington</td>
<td>Gunshot Wound</td>
<td>This is a 92 y.o. female who had a self-inflicted gun shot wound.</td>
</tr>
<tr>
<td>50</td>
<td>Texas</td>
<td>Drug Addiction</td>
<td>This is a 50 year old female who lives in Dallas</td>
</tr>
<tr>
<td>73</td>
<td>Louisiana</td>
<td>Sexually Transmitted Disease</td>
<td>Caution is needed as this disease was contracted by engaging a prostitute and as this person is our governor, we need to be overly cautious not to release this information.</td>
</tr>
</tbody>
</table>

**HIPAA Compliance**

**Full Identifiable Protected Health Information (PHI)**

- With Individual Authorization
- Individual Authorization Waived By An IRB Or Privacy Board
  - Specific Regulated Criteria To Be Met
- Waiver Via Preparatory To Research
  - Researchers Can View But Not Write Down Identifiers
  - Requires Certain Attestations From The Researcher
- Waiver Via Research On Decedents Provision
  - Requires Certain Attestations From The Researcher
- Waiver Via OHRP/FDA Jurisdiction
  - Under Their Legal Authority Outside Of HIPAA
HIPAA Authorizations For Research, Unlike “Regular” Authorizations

• Can Be Combined With Other (Research) Consent Forms
• Can Condition Research-Related Treatment On The Signing Of The Authorization
• Expiration Date/Event Can Be “None” (Note Some State Laws Require A Date/Event)
• Can Temporarily Suspend Patient Access To Some Or All Of Their Records, Reinstated At The Completion Of The Research
• Covered Entity Can Continue Using And Disclosing PHI Obtained Prior To Revocation As Necessary To Protect The Integrity Of The Research Study.

“Preparatory To Research” Provision Of HIPAA

• Examples Or “Preparatory”
  – Preparing A Research Protocol
  – Assisting In The Development Of A Research Hypothesis
  – Aiding In Research Recruitment, Such As Identifying Prospective Research Participants Who Would Meet The Eligibility Criteria For Enrollment Into A Research Study
“Preparatory To Research” Provision Of HIPAA

**Restricions**
- Solely To Prepare A Protocol Or Similar Preparatory Purposes
- PHI Cannot Be Removed From Site
- Documentation That PHI Is Necessary For Research Purposes

**Must Receive From The Researcher The Above Three Representations.**

**Contacting Patients For Recruitment Under “Preparatory To Research”**

**YES:** If The Researcher Is Part Of The Covered Entity’s Workforce.

**No:** If The Researcher Is Not Part Of The Covered Entity’s Workforce Unless...
- IRB/Privacy Board Can Give Partial Waiver To Allow The Release Of PHI For External Researcher To Contact Subjects
- Must Meet Criteria For Waiver Of Authorization But Only Specifically For Contact Purposes.

*[Note, Your Business Concerns Or Irb May Trump Either Of These Even If Allowed By Hipaa]*
HIPAA’s “Accounting For Disclosures” Still Applies In Research

• Disclosures Of PHI (Except By Authorization)
  – Remember, De-identified And Limited Data Sets Are Not Subject To This BUT Preparatory To Research Is

• Logging Requirements
  – Date Of Disclosure
  – Name & Address Of Person/Entity Received
  – Brief Description Of PHI Disclosed
  – Brief Description Of Purpose Or Copy Of Request

HIPAA’s “Accounting For Disclosures” Still Applies In Research

• A Separate Log May Be Used If 50+ Records Were Accessed Containing:
  – Name Of Protocol Or Activity
  – Description Of Research Including Purpose
  – Criteria For Selecting Records
  – Brief Description Of PHI Disclosed
  – Date Or Period Of Time Of Disclosure
  – Date Of Last Disclosure
  – Name, Address And Phone Number Of Sponsor
  – Name, Address And Phone Number Of PI
  – Statement As To May Or May Not Be Disclosed For Further Research

• Given To All Patients Requesting Their Accounting (I.E. “Your Records May Have Been Disclosed For The Following…”)

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Revised Rule Effective March 26, 2013: Future/Unspecified Use Now Allowed As A “Purpose”

• Future/Unspecified Use Now Allowed As A “Purpose”

• Authorization Must “Adequately Describe Such Purposes Such That It Would Be Reasonable For The Individual To Expect That His Or Her Protected Health Information Could Be Used Or Disclosed For Such Future Research.”

• Note, All Required Elements Of Authorizations Are Still Required

HIPAA Compliance

Revised Rule Effective March 26, 2013: Final Rule For “Sale Of PHI”

• Sale Is “A Disclosure Of Protected Health Information By A Covered Entity Or Business Associate, If Applicable, Where The Covered Entity Or Business Associate Directly Or Indirectly Receives Remuneration From Or On Behalf Of The Recipient Of The Protected Health Information In Exchange For The Protected Health Information.”

• Cannot Sell Phi Without Individual’s Authorization Unless Meeting Some Exceptions.
  – Authorization Must State That The Disclosure Will Result In Remuneration To The Covered Entity
  – For Waivers Of Authorization And Limited Data Sets, Can For Sell For Research But Only If Remuneration Received Is A “Reasonable, Cost-based Fee To Cover The Cost To Prepare And Transmit The Data For Such Purposes”.
Not A “Sale”: Paid To Do Research. Data Is Byproduct

A “Sale”, Subject To Authorization Or “Cost Only” Restrictions

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Covered Entity

Researcher

Research Data/PHI

Covered Entity

Researcher

Non Research PHI

Covered Entity

Researcher

Research Data/PHI
Most Discussed Concerns

• Just Because It’s Legal, Doesn’t Make It Ethical
  — Ethics Is In The Eye Of The Beholder
• Consistency With Patient/Provider Expectations
  — E.G. Catholic Hospital Giving Data (Knowing Or Unknowingly) For Contraception/Fertility Research
• Risk Management
  — Publications Consistent With Business
  — Fines For “Unsecured PHI”
• Risk Of “Reidentification Attack”

Risk Testing “Reidentification Attack”

Q: Given The Following Fields, What % Of The Records Can Be Traced To A Specific Individual?
1. [Drug],
2. [Dosage And Refill Information],
3. [Patient Diagnosis],
4. [Patient ZIP Inferred From Pharmacy ZIP],
5. [Prescription Fill Date]

A:

2.3% of individuals could be uniquely identified
6.1% were identifiable to a binsize of 2

Other Tests Of Reidentification Risk

Business/Ethics Considerations

18% Reidentifiable

[Sex]
[Date Of Birth]
[County]


Other Tests Of Reidentification Risk

Business/Ethics Considerations

53% Reidentifiable

[Sex]
[Date Of Birth]
[City, Town, or Municipality]

Other Tests Of Reidentification Risk

Business/Ethics Considerations

[Sex] + [Date Of Birth] + [5 Digit Zip Code] → 87% Reidentifiable


Business/Ethics Considerations

Business Strategy

• Is Your Process Easier To Ask For Forgiveness Than For Permission?
• All Other Laws Still Apply
  – E.G. Stark/Anti-kickback Considerations
Thank You!

- David.Vulcano@hcahealthcare.Com
- 615-268-2638