Operationalizing Government Corrective Action Plans: Aftermath of an OCR Investigation

Presented By:

Emmelyn Kim, MA, MPH, CCRA, CHRC
AVP, Research Compliance & Privacy Officer &

Kathleen McGill, MPA, CTR, CPHQ, CIP
VP, Administrative Operations

The Feinstein Institute for Medical Research

---

Emmelyn Kim is AVP, Research Compliance & Privacy Officer at the Feinstein Institute for Medical Research, Northwell Health. She oversees the research compliance programs including quality assurance, regulatory affairs, export controls and conflict of interest. This includes audits and investigations pertaining to HIPAA, allegations of research non-compliance or misconduct. She reports to the Chief Corporate Compliance Officer and the Board’s Executive Audit and Corporate Compliance Committee.

Kathleen McGill is VP, Administrative Operations at the Feinstein Institute for Medical Research, Northwell Health. She oversees the day to day operations of a large multi-faceted research service line. Kathleen reports to the Chief Medical Officer & Senior Vice President.

Disclaimer

The materials and view expressed in this presentation are the views of the presenters and not necessarily the views of Northwell Health
Audience Ice Breaker & Polling

A Quick Recap

OH NO!!
Learning Objectives

1. Discuss key components of carrying out a Corrective Action Plan (CAP): People, Planning and Process
2. Consider unanticipated government challenges, external resources and cost
3. Discover what complex organizations should consider in their training programs

Discuss key components of carrying out a Corrective Action Plan (CAP): People, Planning and Process
Elements of an Office for Civil Rights (OCR) CAP

Security Management Process
  • Risk analysis

Elements of an Office for Civil Rights (OCR) CAP

Implementation of Process for Evaluating Environmental and Operational Changes
  • Standard Operating Procedure (SOPs)
Elements of a CAP (continued)

Policies and Procedures (P&Ps)
- Distribution and Updating P&Ps
- Minimum Content
- Certifications

Minimum content:
- Uses and Disclosures of PHI [45CFR§164.502(a)]
- Security Management Process [45CFR§164.308(a)(1)(i)]
- Information Access Management [45CFR§164.308(a)(4)]
- Workstation Security [45CFR§164.310(c)]
- Device and Media Controls [45CFR§164.310(d)]
- Encryption and Decryption [45CFR§164.312(a)(2)(iv) & 164.312(e)(2)(ii)]

Health Information Portability and Accountability Act (HIPAA) Training for Workforce
- Certifications
- Tracking existing and new hires
Reporting & Other Requirements

1. Reportable Events
2. Implementation Report
3. Annual Reports
4. Document Retention

People

Our workgroup included senior representatives with *decision making authority* from:

- Organizational Leadership
- Administration/Operations
- Compliance
- Legal
- IT Security/Risk Management
- Public Relations
- Human Resources
- Policy and Training

*The workgroup may include others and will evolve over time*
Planning

- Developing a timeline for the CAP
- Regularly occurring touch points/meetings
- Setting expectations
- Communications

Processes

- Establish smaller working groups to evaluate and develop processes
- Connection to larger organizational Committees
Consider unanticipated government challenges, external resources and cost

Things to Think About

Compliance

- Contact, reporting progress & issues
- Tracking and reporting to OCR
- Reporting upwards
Things to Think About

Legal:
• Dedicated internal legal counsel
• Outside counsel with OCR experience
• Response strategy and time frames

Things to Think About

Operational:
• Administration
• Developing processes

→ Think about hiring a Project Manager
Who is Your Workforce?

Operational:
• Tracking workforce
• Communications
• Reporting to Compliance

Things to Think About

IT Security
• Risk Assessments & timeframes
• Vendors
• Costs
Things to Think About

Education and Training:
• Electronic vs. in-person
• Pilot testing
• Tracking and reporting
• HR and escalation procedures

When you thought you got it all covered...

Changes:
• People (transition planning)
• Process (ensuring stakeholders & leadership are aware of ongoing CAP)

Timing:
• Expectations
• The unknown
## Timelines are complicated

### Post Resolution Obligations

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Provide training to:</td>
</tr>
<tr>
<td>2.</td>
<td>Current workforce (60 days &amp; annually)</td>
</tr>
<tr>
<td>3.</td>
<td>New workforce (90 days &amp; annually)</td>
</tr>
<tr>
<td>4.</td>
<td>LOD workforce (90 days from return &amp; annually)</td>
</tr>
<tr>
<td>5.</td>
<td>Signed compliance certification</td>
</tr>
</tbody>
</table>

### Annual Obligations

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Term I</td>
<td>Conduct an Assessment of potential risks and vulnerabilities to the confidentiality, integrity, and availability of PHI &amp; document security measure taken.</td>
</tr>
<tr>
<td>Term II</td>
<td>Conduct an Assessment of potential risks and vulnerabilities to the confidentiality, integrity, and availability of PHI &amp; document security measure taken.</td>
</tr>
<tr>
<td>Term III</td>
<td>Conduct an Assessment of potential risks and vulnerabilities to the confidentiality, integrity, and availability of PHI &amp; document security measure taken.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Annual report (60 days)</td>
</tr>
<tr>
<td>2.</td>
<td>Submission date:</td>
</tr>
<tr>
<td>3.</td>
<td>Annual report (60 days)</td>
</tr>
<tr>
<td>4.</td>
<td>Submission date:</td>
</tr>
<tr>
<td>5.</td>
<td>Annual report (60 days)</td>
</tr>
<tr>
<td>6.</td>
<td>Submission date:</td>
</tr>
<tr>
<td>7.</td>
<td>Annual report (60 days)</td>
</tr>
<tr>
<td>8.</td>
<td>Submission date:</td>
</tr>
<tr>
<td>9.</td>
<td>Annual report (60 days)</td>
</tr>
<tr>
<td>10.</td>
<td>Submission date:</td>
</tr>
<tr>
<td>11.</td>
<td>Annual report (60 days)</td>
</tr>
<tr>
<td>12.</td>
<td>Submission date:</td>
</tr>
</tbody>
</table>
Guess how far we are...

<table>
<thead>
<tr>
<th>Post Resolution Obligations</th>
</tr>
</thead>
<tbody>
<tr>
<td>HHS/OCR Agreement signed &lt;Date&gt;</td>
</tr>
</tbody>
</table>

| HHS/OCR Agreement signed <Date> | Submit process to evaluate environmental and operational changes in the environment to OCR (1,460 days) | Implement process & submit to workforce members responsible for implementing process by (160 days) | OIR approval of training | OCR approval of Policies and Procedures |

| HHS/OCR Agreement signed <Date> | Submit process to evaluate environmental and operational changes in the environment to OCR (1,460 days) | Implement process & submit to workforce members responsible for implementing process by (160 days) | OIR approval of training | OCR approval of Policies and Procedures |

Discover what complex organizations should consider in their training programs
Focus on Implementing Controls

Communication & Dissemination of Policies

Education & Training Programs for Researchers
• Research orientation/onboarding for researchers
• Ongoing HIPAA training
• Development of tools & guidance
→ Increasing awareness is key

Focus on Implementing Controls (Continued)

Institutional HIPAA Privacy & Security Review Process for Research
• Human Research Protection Program (HRPP)
• Pre-reviews/consultations by Research IT
• Use information from process to inform education and training & guidance documents
Monitoring & Detection

Office of Research Compliance
• Routine reviews and for-cause investigations
• Monitoring PHI
• HIPAA Rounding Audits

Working collaboratively with:
• Research IT Security/Information Systems
• Corporate Compliance
  • Software detection systems
• Researchers
→ Information used to inform education and training

Evaluating Risks

Larger System Level Committees:
• Research Information Security and Compliance (RISC) Committee
• Protected Health Information (PHI) Committee
• IT Risk Governance Committee

Other Sources:
• Internal & external compliance reviews
• Risk Assessments with key stakeholders
• Evaluating regulatory environment and market trends
→ Information used to inform education and training for broader group
Contact us:

Emmelyn Kim
Email: ekim@northwell.edu
ekim@northwell.edu
Kathleen McGill
Email: kmcgill@northwell.edu