# Operationalizing Government Corrective Action Plans: Aftermath of an OCR Investigation

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## Audience Ice Breaker & Polling

## A Quick Recap

## 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)]

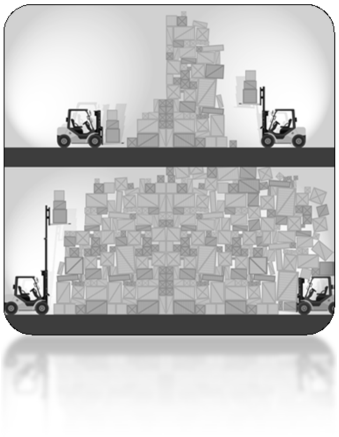
# Elements of a CAP (continued)

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
5. Breach Provisions



# People

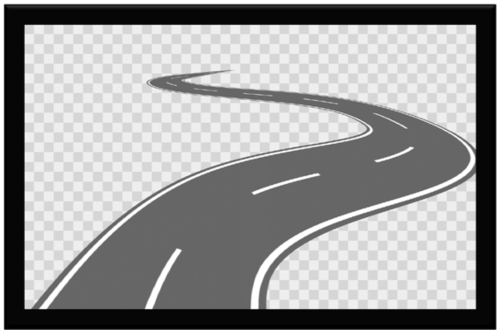
Our workgroup included senior representatives with ***decision making authority*** from:

- 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*

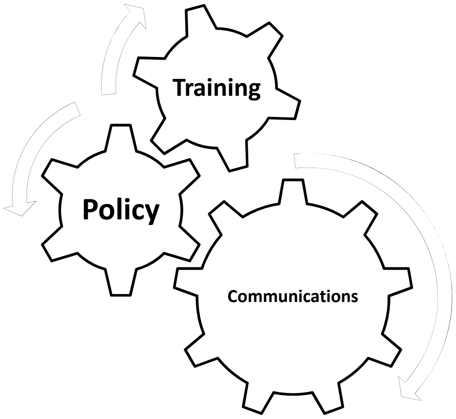
# Planning

- 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:

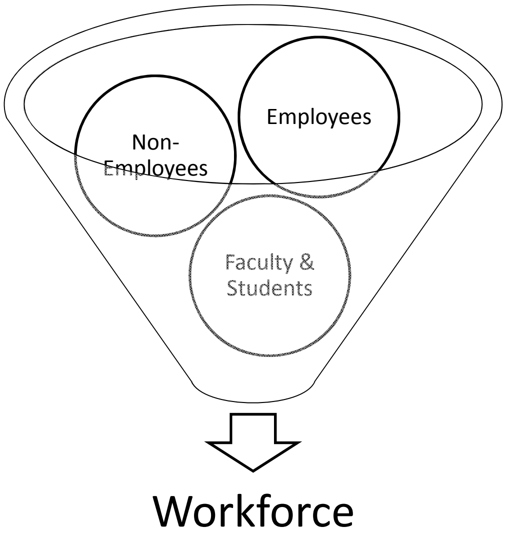
- Administration
- Developing processes

→ *Think about hiring a Project Manager*

# Who is Your Workforce?

Operational:

- Tracking workforce
- Communications
- Reporting to Compliance



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# Things to Think About

IT Security

- Risk Assessments & timeframes
- Vendors
- Costs

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## 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…

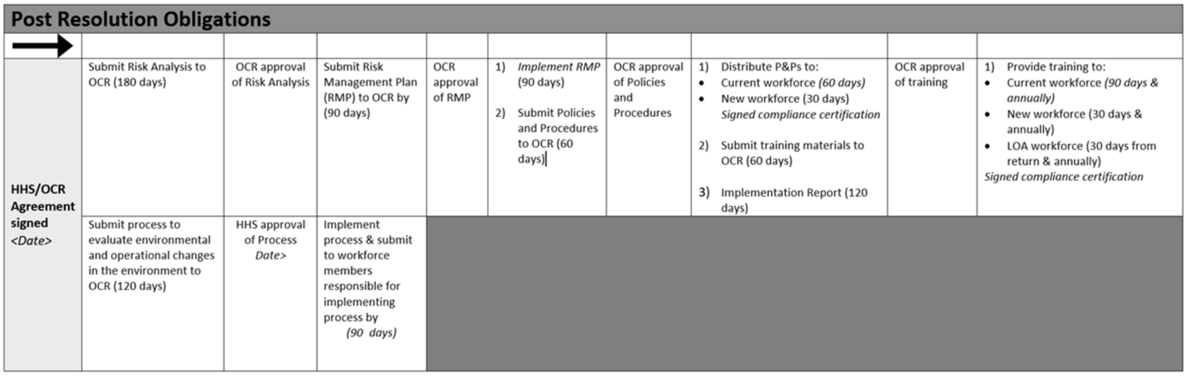
Changes:

- People (transition planning)
- Process (ensuring stakeholders & leadership are aware of ongoing CAP)

Timing:

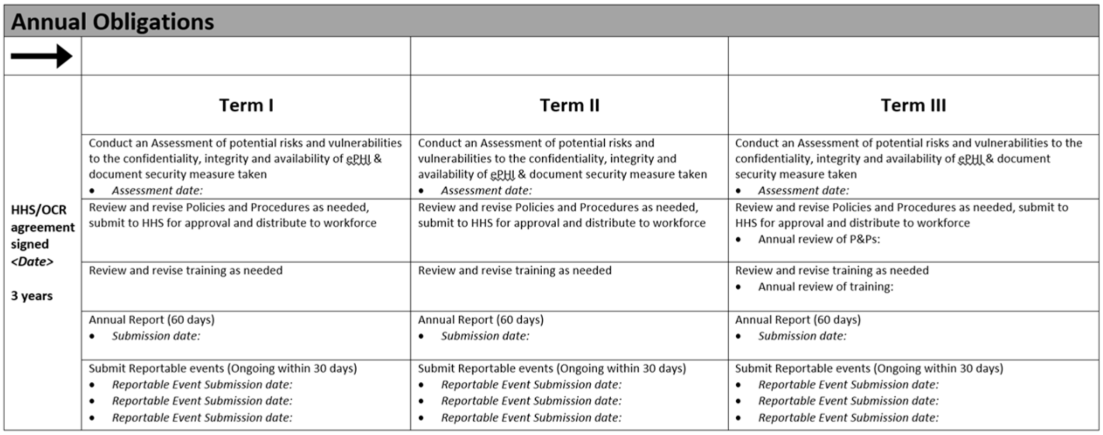
- Expectations
- The unknown

# Timelines are complicated



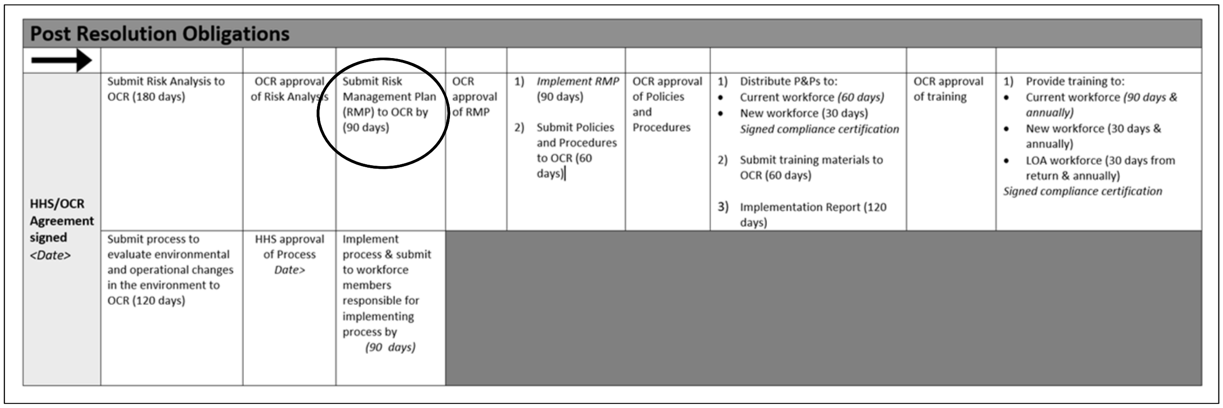
| Post Resolution Obligations | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| → | | | | | | | | | |
| **HHS/OCR Agreement signed** *<Date>* | Submit Risk Analysis to OCR (180 days) | OCR approval of Risk Analysis | Submit Risk Management Plan (RMP) to OCR by (90 days) | OCR approval of RMP | 1) *Implement RMP* (90 days)<br>2) Submit Policies and Procedures to OCR (60 days) | OCR approval of Policies and Procedures | 1) Distribute P&Ps to:<br>• Current workforce *(60 days)*<br>• New workforce (30 days)<br>*Signed compliance certification*<br>2) Submit training materials to OCR (60 days)<br>3) Implementation Report (120 days) | OCR approval of training | 1) Provide training to:<br>• Current workforce *(90 days & annually)*<br>• New workforce (30 days & annually)<br>• LOA workforce (30 days from return & annually)<br>*Signed compliance certification* |
| | Submit process to evaluate environmental and operational changes in the environment to OCR (120 days) | HHS approval of Process *Date>* | Implement process & submit to workforce members responsible for implementing process by *(90 days)* | | | | | | |

# Timelines are complicated



| Annual Obligations | | | |
|---|---|---|---|
| → | | | |
| | **Term I** | **Term II** | **Term III** |
| **HHS/OCR agreement signed** *<Date>*<br>**3 years** | Conduct an Assessment of potential risks and vulnerabilities to the confidentiality, integrity and availability of ePHI & document security measure taken<br>• *Assessment date:* | Conduct an Assessment of potential risks and vulnerabilities to the confidentiality, integrity and availability of ePHI & document security measure taken<br>• *Assessment date:* | Conduct an Assessment of potential risks and vulnerabilities to the confidentiality, integrity and availability of ePHI & document security measure taken<br>• *Assessment date:* |
| | Review and revise Policies and Procedures as needed, submit to HHS for approval and distribute to workforce | Review and revise Policies and Procedures as needed, submit to HHS for approval and distribute to workforce | Review and revise Policies and Procedures as needed, submit to HHS for approval and distribute to workforce<br>• Annual review of P&Ps: |
| | Review and revise training as needed | Review and revise training as needed | Review and revise training as needed<br>• Annual review of training: |
| | Annual Report (60 days)<br>• *Submission date:* | Annual Report (60 days)<br>• *Submission date:* | Annual Report (60 days)<br>• *Submission date:* |
| | Submit Reportable events (Ongoing within 30 days)<br>• *Reportable Event Submission date:*<br>• *Reportable Event Submission date:*<br>• *Reportable Event Submission date:* | Submit Reportable events (Ongoing within 30 days)<br>• *Reportable Event Submission date:*<br>• *Reportable Event Submission date:*<br>• *Reportable Event Submission date:* | Submit Reportable events (Ongoing within 30 days)<br>• *Reportable Event Submission date:*<br>• *Reportable Event Submission date:*<br>• *Reportable Event Submission date:* |

## Guess how far we are…



| Post Resolution Obligations | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
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## Discover what complex organizations should consider in their training programs

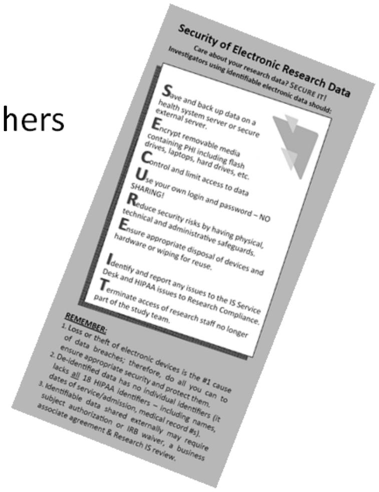
## Focus on Implementing Controls

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*



**Security of Electronic Research Data**

**Care about your research data? *SECURE IT!***

**Investigators using identifiable electronic data should:**

**S**ave and back up data on a health system server or secure external server.

**E**ncrypt removable media containing PHI including flash drives, laptops, hard drives, etc.

**C**ontrol and limit access to data

**U**se your own login and password – NO SHARING!

**R**educe security risks by having physical, technical and administrative safeguards.

**E**nsure appropriate disposal of devices and hardware or wiping for reuse.

**I**dentify and report any issues to the IS Service Desk and HIPAA issues to Research Compliance.

**T**erminate access of research staff no longer part of the study team.

**REMEMBER:**

1. Loss or theft of electronic devices is the #1 cause of data breaches; therefore, do all you can to ensure appropriate security and protect them.
2. De-identified data has no individual identifiers (it lacks all 18 HIPAA identifiers – including names, dates of service/admission, medical record #s).
3. Identifiable data shared externally may require subject authorization or IRB waiver, a business associate agreement & Research IS review.

## 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*

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