



Research PHI in the Cloud: Human Subjects Protection Transformed

Presented by



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Objectives

- Discuss the need for a secure cloud-based environment in which to manage PHI from research studies.
- Outline a process to create a secure cloud environment in which to facilitate large PHI data set sharing and manipulation.
- Ponder questions regarding research PHI data governance and data ownership in an academic medical center environment.

UK HealthCare – The Power of Advanced Medicine



UK HealthCare Pillars

Mission

UK HealthCare is committed to the pillars of academic health care—research, education and clinical care. Dedicated to the health of the people of Kentucky, we will provide the most advanced patient care and serve as an information resource. We will strengthen local health care and improve the delivery system by partnering with community hospitals and physicians. We will support the organization's education and research needs by offering cutting edge services on par with the nation's best provider.

Vision

The vision of UK HealthCare is to achieve national recognition as a Top 20 public academic health center, providing optimal multidisciplinary health care and developing advanced medical therapeutics for the people of Kentucky and surrounding regions.



Solving the Unsolvable

- **Research is the key to the future of medicine.** At UK HealthCare, our researchers are working every day to find answers where there were no answers before.
- As an academic research institution, our physicians as well as pharmacists, nurses, and other healthcare professionals are continuously pursuing the next generation of cures, treatments, protocols and policies. Their discoveries have the potential to change what's medically possible within our lifetimes. At the same time, our educators and thought leaders in health policy and delivery are transforming the healthcare landscape in Kentucky to provide the right care, in the right place, for everyone in the state.
- The **UK Markey Cancer Center** has earned designation by the National Cancer Institute – the most prestigious designation possible. And because of that, we have access to new treatments not yet generally available, and to clinical trials most other hospitals do not.



Background

- Prominent researcher with IT expertise obtained large grant
- Grant provides for access and usage of extremely large dataset containing protected health information (PHI)
- Researcher identified Amazon Web Services (AWS) as a likely solution in which to store and manipulate the large dataset.
- Researcher obtained AWS funds to establish his own AWS account.
- Problem: Not all AWS services are HIPAA-eligible.

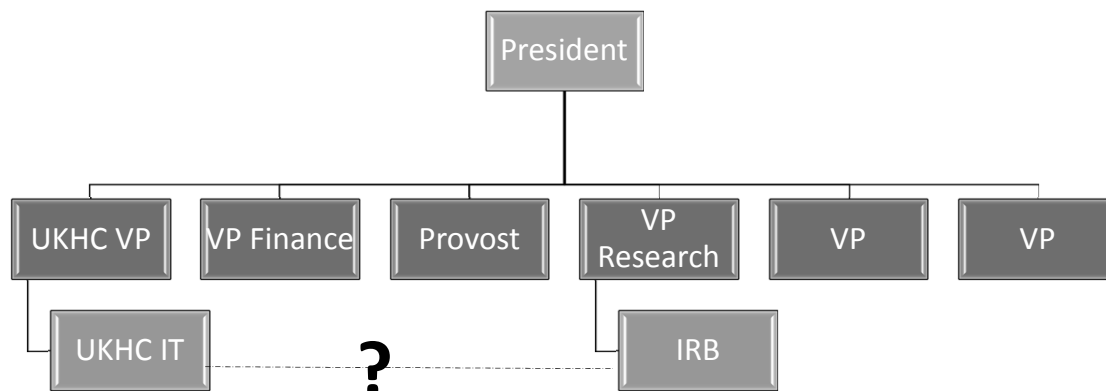
The Opportunity of the Cloud

- Build a process that leverages UKHC IT to acquire and implement Amazon Web Services to support research.
 - Integrating IT services into research is a significant opportunity.
 - IT has a stake in research activities as the ultimate owners of data and data security.
 - Cloud services (like AWS) are quickly changing the research landscape and creating new vectors of data breaches.

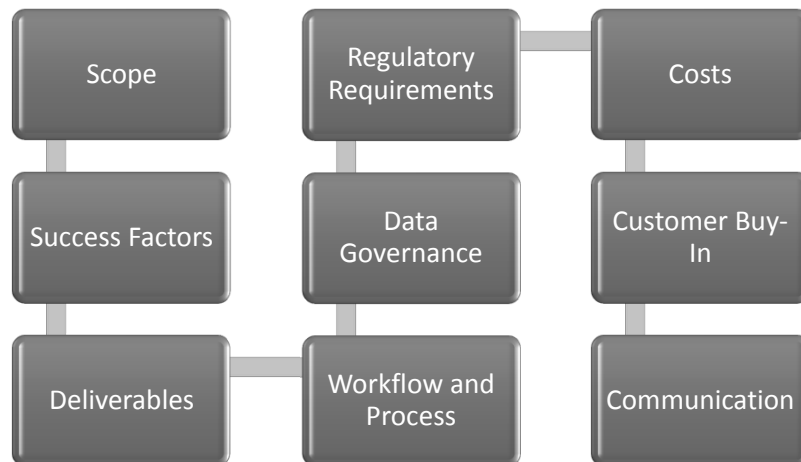
Amazon Web Services for Research Workgroup

Charge:	Membership:	Tasks:
<ul style="list-style-type: none"> To develop a standard process of acquiring permission and the appropriate configuration of Amazon Web Services 	<ul style="list-style-type: none"> IT Security IT Architecture Privacy IT Data Governance Research Data Governance Office of Research Integrity Research IT 	<ul style="list-style-type: none"> Create workflows and processes to operationalize acquisition and configuration of AWS resources for research activities. Establish governance process. Resolve related issues that may arise.

University of Kentucky



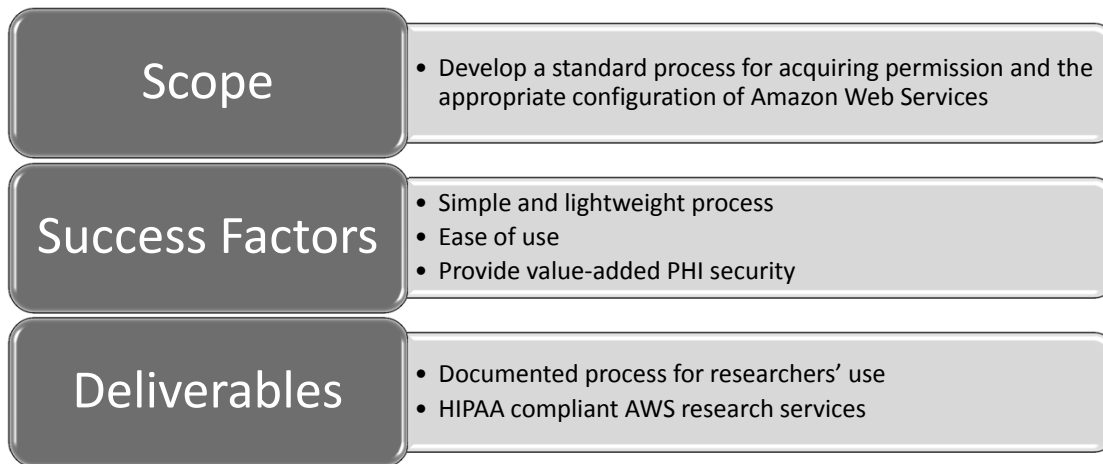
Project Components to Consider



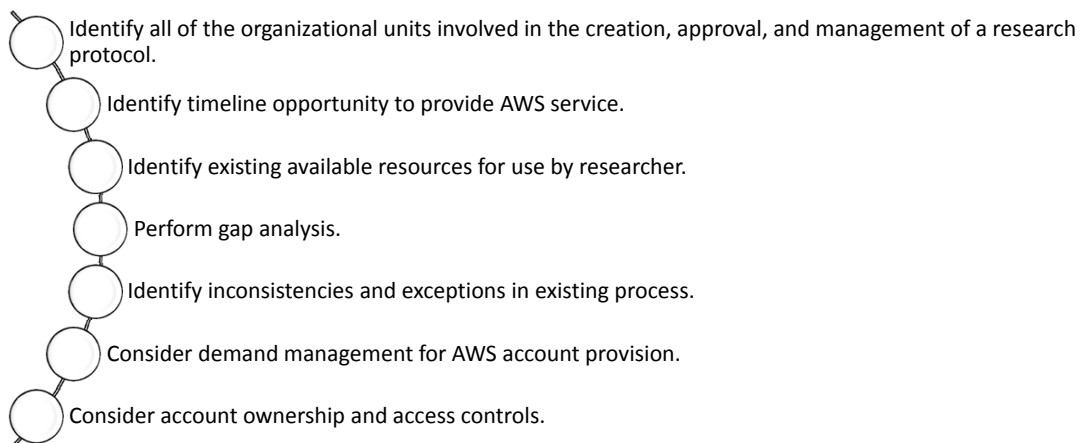
AWS Project Topic Overview

#	Topic	Considerations
1	Scope	Develop standard practiced for AWS use for research PHI.
2	Success Factors	Simple and lightweight process, ease of use
3	Deliverables	Documented process for researchers' use, secure PHI
4	Workflow and Process	IRB Processes, IT Processes, Researcher Processes
5	Data Governance	Research Data, Health Care Data
6	Regulatory	HIPAA, OHRP, CAP, GINA, Records Retention
7	Costs	FTEs, financial, demand, usage, lifecycle
8	Stakeholder buy-in	Researchers, Security, Privacy, Demand, Architecture, IRB
9	Communication	Who, what, when, where, why, and how?
10	Go-Live	Contingencies, Risks

Identify the Needs



Workflow and Processes



Data Governance and Risk

Who controls the data governance process?

Who owns the data?

How does the institutions structure determine data ownership and governance?

Does the research protocol dictate additional data ownership considerations?

Are there intellectual property issues to consider?

How long must the research/PHI data be maintained and protected?

Regulatory Considerations On Prem. vs. Cloud

- Privacy Rule
- OHRP
- HITECH
 - Third Party Risks
 - BAA's and Breaches
- CAP requirements for Genomic Data
- GINA
- IT Security standards
- Auditing, Monitoring, Remedy

Additional HHS Laws & Regulations

Find laws and regulations on civil rights, privacy rights, research, fraud prevention and detection, freedom of information, tribal matters, employment, and more.



www.hhs.gov

Costs

Live data vs. archived data

Time and effort costs

Can you use research overhead dollars?

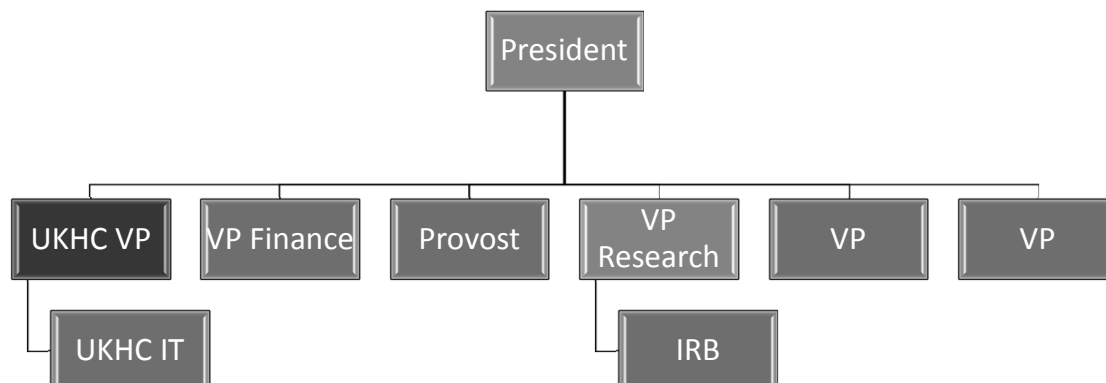
Project costs vs. department costs?

Should it depend on the volume?

Can you build archiving fees into the project budget?

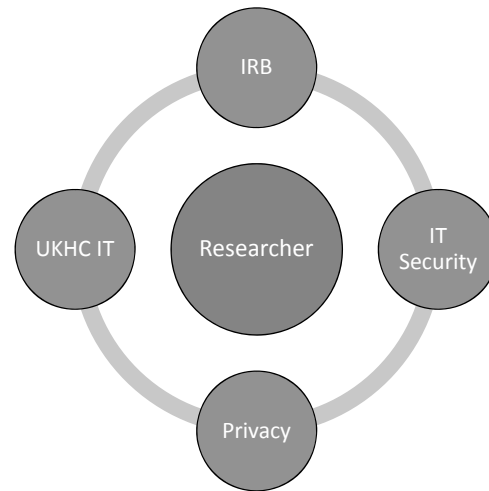
Can you bill for unfunded projects?

Who pays for this???



Stakeholder Buy-in

If researchers don't see value-added and experience ease of use, they will find a potentially non-compliant solution instead of adopting the new process.



Cloud-Backed
Research
Platform:
Background and
Purpose

Guiding Principles

- **Value Proposition** – Process should add value for research activities and investigators.
- **Easy-to-Follow** – Process should not be onerous for users to follow.
- **Foster Innovation** – Process should not be so rigid to limit capabilities.
- **Accelerate Development** – Process should optimize processes for creating tools and resources to quicken time to delivery.

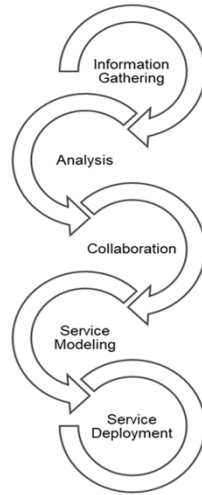


Guiding Principles (con't)

- **Shared Resources and Reuse** - Slow the sprawl of data and Control technical diversity
- **Cost Containment** – Process should help find and eliminate costly redundancies and inefficient use of resources.
- **Risk Containment** – Process should help find and mitigate risks for Investigators and IT.
- **Foster Collaboration** – Process should allow for 3rd party integrations and new resources.



Our Focus



1. Information Gathering – Understanding the research process in general.
2. Analysis – Identifying opportunities to leverage IT in existing process.
3. Collaboration – Working with the UKHC Research Community of Practice for buy-in and support.
4. Develop a Service Model – Design how to deliver cloud-hosted services to empower research.
5. Service Deployment – Deliver a new capability to support research



Current Research Protocol Approval Process

- Pre-Submission
- IRB Review
- IRB Approval
- Data & Infrastructure Development
- Research Project Start – End
- Destruct/Turn Off Environment

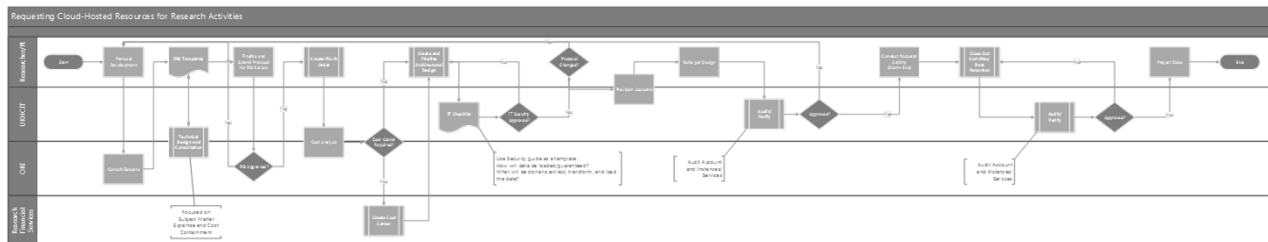


Research Process with IT Support

- Pre-Submission
- IRB Review
 - Technical Review
- IRB Approval
- Acquire AWS Resources/Environment
- Data & Infrastructure Development (IT Support if Needed)
- Audit (including IT)
- Research Project Start – End
- Destruct/Turn Off Environment (IT Support if Needed)
- Verify/Audit (including IT)



Workflow



Moving Forward

- We have the opportunity to work with the Research subcommittee of IT Data Governance and other Data Groups.
- Focus on how to operationalize the process within the business workflow.
 - IT cannot drive the process, but we can catalyze adoption and support the effort.
- Focus on Governance of Process and operations.
 - Auditing, monitoring, cost containment, etc.



Service Models to Explore

Advise and Support

- IT Advises and offers Data Services with SLAs, PI Primarily responsible for design, development and implementation.

Consultation and Subject Matter Expertise

- IT works in collaboration with the PI. Investigator leads effort and pulls in IT as needed for some design and development.

Partnership Model

- IT and Investigators jointly design, build and implement the environment and resources. Accountability shared between IT and Principle Investigator.



More Service Models to Explore

IT-Led Implementation

- IT accepts work order to design, build, and implement resources and environments under direction of the Principle Investigator. Current Lean is IT will not provide this level of service.

Concierge Service

- Principle Investigator hands off all design, development, and implementation activities for IT to build as a turn-key solution. Current Lean is IT will not provide this level of service.



Questions?

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