Where is the Data? Risks of Data Location, Storage and Protection of Sensitive Protected Health Information

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Session Objectives

- Identify how to capture your institution's information asset landscape and identify sensitive data and PHI.
- Discuss research data security and storage plans as an effective method for monitoring sensitive information, regardless of form, across the institution.
- Highlight considerations regarding data transfers between institutions when faculty arrive and leave.
- Get tips for safeguarding your institution.

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Now, a little about us you…

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Knowing where your sensitive data is takes a few steps…

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1st Step: IDENTIFY YOUR INFORMATION ASSET LANDSCAPE

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Um, excuse me, do what?!

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How!?!

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How!?! (cont'd.)

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Survey and Inventory

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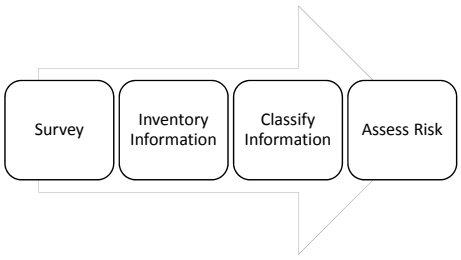

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Conduct a Privacy Impact Assessment

A **Privacy Impact Assessment**, or PIA, is an analysis of how sensitive information is collected, used, shared and maintained at your institution.

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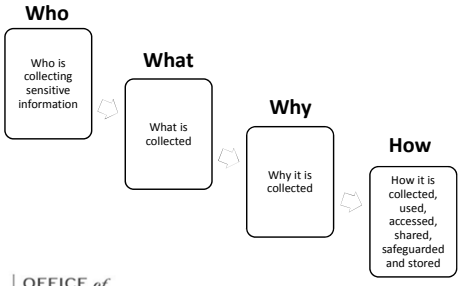
A PIA identifies:



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A PIA is a decision tool to identify and mitigate institutional privacy risk:

- Ensure legal, regulatory and institutional policy compliance.
- Determine associated risks and effects.
- Evaluate protections and alternative processes to mitigate potential privacy risks.

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Does your organization currently conduct PIAs or otherwise inventory sensitive data?

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Tips

- Identify institutional partners
- Conduct PIAs
  - Survey the institution for sensitive information
  - Inventory sensitive data and related information asset management practices
  - Risk assess information management
- Identify gaps against compliance requirements
- Engage institutional partners to address gaps
- And….

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2nd Step: MAINTAIN ONGOING CONTROL

Annual Update Model

- Provides information if data has moved or system has changes
- Can be tied to IRB renewal
- Is research unit- or other owner-driven
- Serves as a central repository for annual update information
- Management takes responsibility for knowing where data resides!

Duke's Research Data Storage Plans (RDSP)

- Tied to submitted protocols
- Specify storage location
- Identify classification of data being collected
- Reviewed by IT personnel
- Research unit sign-off
- Included in eIRB with study protocol information
- Study team responsible for plan accuracy

Other Protection Tools:

- Data Loss Prevention®
  - January 2013
  - The Data Loss Prevention program: Software that allows for the protection of sensitive and confidential information on the Duke Health Network.
  - Monitors sensitive information, such as PHI and financial information, that leaves the institution.
    - Email encryption.
    - No sensitive information in the subject line.

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Other Protection Tools:

- FairWarning®
  - Privacy surveillance tool Compliance employs to systematically audit and review EHR and billing access.
  - Assists with identifying unauthorized faculty and staff access of household members', VIPs' and others' records.
  - Patient authorization: Staff may download the Authorization to Protected Health Information Form from HIM webpage or may request the form from HIM. MUST be completed and signed by the patient / patient representative and forwarded to HIM.

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Does your institution have something similar to an RDSP?

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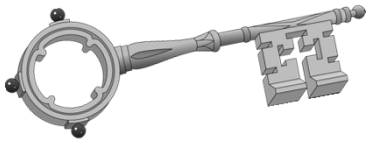
Does your institution have other data loss prevention mechanisms?

3rd Step: COMMUNICATE AND MONITOR

Communication is the



to effective compliance

Ensure everyone gets the message!

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To get to all, it takes different paths…

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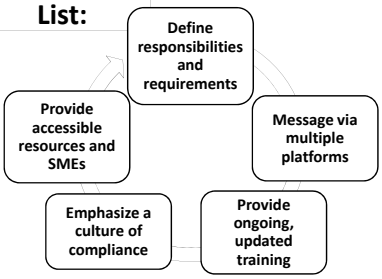
The 'To Do' List:



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How do you communicate?

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And to mitigate risk and protect the institution…

monitor.

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Activities to Monitor

- Collection and use of PHI without subject authorization and/or a HIPAA waiver.
- Storing research data, especially ePHI, on unencrypted computers and/or portable devices.
- Storing research data in non-institutionally approved and/or managed locations.

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Activities to Monitor (cont'd.)

- Retention of Social Security numbers in subject files without an authorized exception.
- Missing ICFs, source documents or other documents containing PHI.
- Failing to adhere to the minimum necessary standard.
- Improper disposal and/or destruction of PHI.

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Activities to Monitor (cont'd)

- Disclosing PHI without the appropriate agreements executed and/or without authorization.
- Unencrypted transmission of PHI and/or other sensitive electronic information.
- Use of unapproved, unmanaged copy or fax machines.
- Use of personal email (Gmail, Yahoo, etc.) for institutional business.

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Faculty Arrival

Things to consider:

- What are individuals bringing with them?
  - Data (Did subjects consent to transfer of identifiable data?)
  - Samples (level of identification)
  - Equipment (what data may still reside on equipment from another institution)
- Where are they coming from?
  - Domestic
  - International

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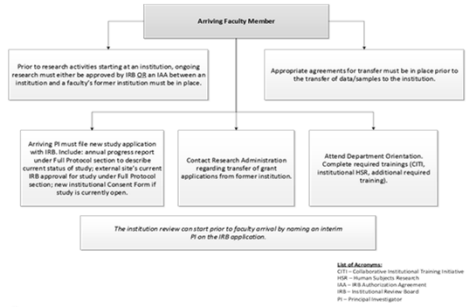

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Faculty Departure

Things to consider:

- Ongoing status on the project(s)
- Level of future involvement
- What do they want to take with them?
  - Samples / data / equipment
- Where are they going?
  - Domestic / international

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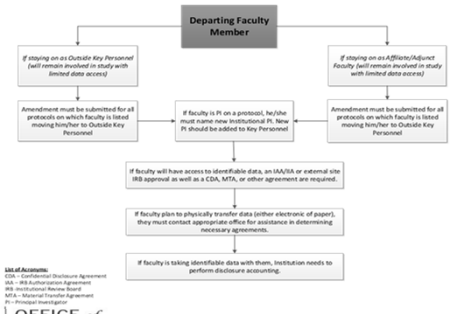

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Questions?

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- Flow charts adapted from the Duke Department of Community and Family Medicine Faculty Arrival and Departure Flowsheet https://oarc.duke.edu/sites/default/files/documents/Faculty%20Arrival%20and%20Departure%20Flowchart%20042216.pdf

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