THE YIN AND YANG OF COMPLIANCE IN THE CLOUD

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The Yin and Yang of Compliance in the Cloud

Researchers have requirements to share data
  • This allows for peer review and secondary research
  • Requirement of funding agencies

Researchers have requirements to protect data
  • Protect human subjects, intellectual property, national security
  • Ensure data integrity for research data
  • Requirement of funding agencies

Sharing and protecting, like yin and yang, seem in opposition, but are complementary and interdependent.
The Yin and Yang of Compliance in the Cloud

CONTENTS

• Introduction
• Research Data and the University
• Yin and Yang, School of Dentistry
• Information Security Requirements for Research
• Secure Data Management and Collaboration Tools
• Conclusion
RESEARCH DATA AND THE UNIVERSITY: IP, DATA INTEGRITY, COMPLIANCE AND SHARING

Earl B. Beutler
CEO, LabArchives, LLC
Research Data and the University

• Protecting Intellectual Property
  – Breakthrough discoveries are of higher financial value than ever
  – Bayh-Dole Act and the value of data
  – Alternative revenue streams to support research as other sources dry up
Research Data and the University

• Ensuring Data Integrity
  – Data Integrity and Conflicts of Interest
    • Fabrication
    • Falsification
    • Misrepresentation (partial results)
    • Plagiarism
  – Data Reproducibility
    • Nature 482:531, 2012, Bagley and Ellis
    • PLOS One, May 15, 2013, Mobley et al
Research Data and the University

• Regulatory Compliance
  – HIPAA
  – Other privacy regulations, FERPA
  – 21 CFR Part 11
Research Data and the University

• Data Sharing Compliance
  – Mandates from the Federal Government
    • 15 funding agencies
    • Requires Federal agencies to make the results of federally funded scientific research available to and useful for the public, industry, and the scientific community.
    • Each with different regulations
Research Data and the University

• Data Sharing Compliance (http://www.ahrq.gov/funding/policies/publicaccess/index.html)
  – White House Office of Science and Technology Policy (OSTP): "Increasing Access to the Results of Federally Funded Scientific Research."
  – Agency for Healthcare Research and Quality (AHRQ) Public Access Policy promotes the following objectives (among others):
    • Establish AHRQ's commitment to public access to scientific research results.
    • Ensure that all extramural researchers receiving AHRQ grants, cooperative agreements, and contracts for scientific research and intramural researchers develop data management plans, as appropriate, describing how they will provide for long-term preservation of and access to scientific data in digital format.
    • Ensure the expedited translation of research results into knowledge, products, and procedures to improve health.
    • Facilitate the education of new researchers and enable the exploration of topics not envisioned by the initial investigators.
    • Permit the creation of new datasets when data from multiple sources are combined.
Research Data and the University

Research Data and the University

“To the extent feasible and consistent with applicable law and policy….digitally formatted scientific data…supported wholly or in part by Federal funding should be stored and publicly accessible to search, retrieve and analyze.”
The sharing and preservation of data advances science by broadening the value of research data across disciplines and to society at large, protecting the integrity of science by facilitating the validation of results, and increasing the return on investment of scientific research.

- Protecting confidentiality and personal privacy are paramount, and no changes will be made to existing policies that would reduce current protections.
- Proprietary interests, business confidential information, intellectual property rights, and other relevant rights will continue to be appropriately protected.
Research Data and the University

- The costs and benefits of data management should be considered in policy development and implementation. It is important to note that not all digital scientific data need to be shared and preserved. A fundamental determinant of the need to share and preserve data is the further insight to be gained from increased public access.

- Data management planning should be an integral part of research planning, and planning for data collection or creation and management should take into account downstream data processing and dissemination.
Research Data and the University

Research Data and the University

• “To the extent feasible……research supported wholly or in part by NSF funding should be stored and publicly accessible to search, retrieve and analyze.”
• “…..proposals must include a supplementary document of no more than two pages labeled “Data Management Plan.” This supplement should describe how the proposal will conform to NSF policy on the dissemination and sharing of research results…”

January 18, 2011
Professional Edition

- Support research staff productivity and efficiency
- Data stored with multiple redundancy
- ALL data preserved and versioned on U.S. based servers
- 3rd party (NIST) date and time stamp
- Support funding agencies' Data Stewardship and Data Management Plans requirements (i.e. NIH, NSF)
- Standard HTML format
- Single Sign on via Shibboleth
LabArchives will improve **compliance** with your data management plans, **secure** your research data and **ensure control** over your intellectual property.

- Replace the Paper Notebook and Lab Manuals to better protect, monitor, engage and evaluate your PI teams’ lab work
- Complete audit control - tracks and stores ALL revisions, by users, for every entry - NO entry can be deleted - Protect IP -
- Notebook user access can be managed to allow access rights to certain notebooks, pages and/or entries
- Create and adhere to funding agency Data Management Plans which require data sharing (via public URL or DOI)
“LabArchives has been transformative for researchers at the University of Sydney, delivering multiple benefits. Fundamentally, researchers have found that LabArchives integrates seamlessly into their research practices, rather than changing the way they do research. Uniformly it is saving people time and making their research more efficient. For some that means increasing the amount of experimentation they do each day, and with others it has enabled more thorough analysis of research findings and writing. LabArchives has supported researchers in organizing their information in ways that are impossible with normal files, giving them the ability to search all their experiments and manage data and IP much more coherently, for example. One researcher even commented that LabArchives is like having their own Personal Assistant in the lab!“

- Dr. Andrew Black, Director, Research Development and Collaboration, University of Sydney

"UT Southwestern Medical Center selected LabArchives as a platform for our research community to maintain their valuable research data as well as to facilitate collaborations and assist in compliance with government regulations. It has been a very smooth and easy transition with little impact on Information Resources, and I have received very positive feedback from our investigators in using LabArchives“

- Dr. Dipti Ranganathan, Associate Vice President, Academic Information Systems, UT Southwestern Medical Center
LabArchives and Data Sharing

- Share within your lab, in the University, or with collaborators
- Share publicly
  - URL
  - Digital Object Identifier (DOI)

LabArchives includes a robust API to provide integration with institutional resources
### Table of Contents

<table>
<thead>
<tr>
<th>Phenotypic Mutations - Table of Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gene</strong></td>
</tr>
<tr>
<td>----------</td>
</tr>
<tr>
<td>TauC350I</td>
</tr>
<tr>
<td>RhoC</td>
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<tr>
<td>Ead2</td>
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<td>Tpt1</td>
</tr>
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</tr>
<tr>
<td>Col24</td>
</tr>
<tr>
<td>Mef2c</td>
</tr>
</tbody>
</table>
LabArchives – Sample DOI
LabArchives – DOI Assignment
The Yin and Yang of Compliance
University of Michigan School of Dentistry

School of Dentistry
Compliance within the School
Dental Research and the Cloud
EHR Cloud and Compliance
Mission - Advancing health through education, service, research, and discovery

Facts
EDUCATION! EDUCATION! EDUCATION! EDUCATION!
Compliance Agreements

Compliance Expectations and Agreements

- Online tool Foliotek/MiLinc that automates education and agreements with email notification

Complete Confidentiality

Complete Infection Control
Student Education

Pre-acceptance Interviews
Day One Orientation
Electronic Health Record Training
Compliance Agreements
Dental Research

Bigmouth Dental Data Repository https://cohri.uth.tmc.edu/
  • Oral health database, de-identified data contributed by dental schools who are part of the Consortium for Oral Health Research and Informatics (COHRI)

FaceBase funded by the National Institute of Dental and Craniofacial Research (NIDCR)
  • https://www.facebase.org/
Research Data Storage

Technical Guidance for Safe Storage

Campus Storage Solutions
Local NAS storage
BOX for Data Collaboration
ELN’s Electronic Notebooks: LabArchives, iLabber, Zim
LIMS – Laboratory Information Management Services
The Cloud
Future Challenges

BYOD - Cloud

Disk Encryption

De-identified Data for Research
EDUCATION! EDUCATION! EDUCATION! EDUCATION! EDUCATION!
The Yin and Yang of Compliance
Information Security Requirements for Research

- Information Security in the Research Enterprise
- Information Security Requirements in the Research Enterprise
- Education on Information Security Requirements
- Secure Data Management and Collaboration Tools
Information Security in the Research Enterprise

• Many times handled directly by researchers
• Human subjects and medical research
• Institutional Review Boards
• Research teams using template language from prior applications
• Institutions need to review information security requirements as part of their research administration. You may need to review RFP, RFP amendments, contracts, contract amendments, etc to identify the security requirements.
  – You may already have a contract/grant with high security requirements!
• High security requirements only on a small subset of research data
• Not the only compliance requirements!
Information Security Requirements in the Research Enterprise

• Laws, regulations, guidelines, oh my!
  – Federal Sentencing Guidelines – guidelines around a compliance culture to protect the organization
  – Dual-Use, ITAR, Export Control, Select Agents, Nuclear Regulatory Commission, FDA CFRPart11, HIPAA, Common Rule, etc.

• Information Security in NIH, NSF, and others!
  – NIH – Template FISMA requirements in RFPs and in Grants policy
  – FDA – CFRPart 11 on Electronic Records and Electronic Signatures
  – DOD – Now using FISMA Low, including non-classified/public research
  – Different requirements between different agencies
EDUCATION! EDUCATION! EDUCATION! EDUCATION! EDUCATION!
Education on Information Security Requirements

• Start with an enterprise security awareness program and build the research aspects into the program.

• Integrate security where the researchers already are!
  – Responsible Conduct for Research – Work with researchers directly to help them better understand the requirements
  – Safety training – if they are already getting mandated safety training, adding a short presentation on information security might help
  – Research Administration – The people across campus responsible for institutional research administration and potentially in schools and colleges
  – Research Teams – outreach to the people involved with the research
Secure Data Management and Collaboration Tools

- Identify the security requirements
- Identify work or data flows that need to be secured
- Is there a tool already available or approved to meet the researchers requirements for sharing and security?
- If not, can a proposed tool be vetted and approved for usage in the research?
  - Can this tool be used at other campuses to help them?
  - If so, this might be a good candidate for inclusion in the NET+ program.
LabArchives in the NET+ Program

- Service Type(s): Software as a Service
- Subscribers: Internet2 Member
- Sponsors: Cornell University
- Phase: Early Adopter
- Email: netplus@internet2.edu
- Contact(s): Matthew Buss
- http://www.internet2.edu/products-services/cloud-services-applications/lab-archives/
IceHealth in the NET+ Program

- Service Type(s): Software as a Service
- Subscribers: Internet2 Member
- Sponsors: University of Michigan
- Phase: Early Adopter
- Email: netplus@internet2.edu
- Contact(s): Matthew Buss
- http://www.internet2.edu/products-services/cloud-services-applications/ice-health-systems/
What is Internet2 NET+ Services about?

- A partnership to provide a portfolio of solutions for Internet2 member organizations that are cost-effective, easy to access, simple to administer, and tailored to the unique, shared needs of the community:
  - Define a new generation of value-added services
  - Leverage the Internet2 R&E Network and other services such as InCommon
  - Drive down the costs of provisioning/consuming services
  - Provide a strategic partnership with service providers (new service offerings).
  - Leverage community scale for better pricing and terms
  - Develop solutions that meet performance, usability, and security requirements
  - Provide a single point of contracting and provisioning
How NET+ Providers are Selected:

ALWAYS Sponsored by Internet2 Member Campus

- Can the services scales at least nationally?
- Can it be delivered over global R&E networks?
- Develop a business model that scales globally and serves significant portion of community?
- Will provider work with community to meet unique R&E needs today and into the future?
- Adopts R&E federated identity standards?
- Commit to community’s Security, Privacy, Compliance, and Accessibility needs?
- Supportive of common, community contracting terms and conditions (negotiate once, use many times)
Requirements of Service Providers

• Identified Sponsor: CIO or other senior executive from a member institution
• Membership in Internet2 and InCommon Federation
• Adoption of InCommon - Shibboleth/SAML2.0 and Connection of services to the R&E Network
• Completion of the Internet2 NET+ Cloud Control Matrix
• Commitment to:
  ▪ A formal Service Validation with 5-7 member institutions
  ▪ Enterprise wide offerings and best pricing at community scale
  ▪ Establishing a service advisory board for each service offering
  ▪ Community business terms (Internet2 NET+ Business and Customer agreements)
  ▪ support the community’s security, privacy, compliance and accessibility obligations
• Willingness to work with the Internet2 community to customize services to meet the unique needs of education and research
NET+ Service Validation Components

• Functional Assessment
  – Review features and functionality
  – Tune service for research and education community

• Technical Integration
  – Network: determine optimal connection and optimize service to use the Internet2 R&E network
  – Identity: InCommon integration

• Security and Compliance
  – Security assessment: Cloud Controls Matrix
  – FERPA, HIPAA, privacy, data handling
  – Accessibility

• Business
  o Legal: customized agreement using NET+ community contract templates
  o Business model
  o Define pricing and value proposition

• Deployment
  o Documentation
  o Use cases
  o Support model
Expanded Services for Researchers

• Infrastructure services with research use cases
  – Several research oriented workshops on “big data” topics

• New services under development
Conclusions

• Awareness on campus to sharing and data security requirements is critical
• Need tools and processes that meet the sharing and security requirements
  – LabArchives and ICE Health are models
• If you don’t provide the tools, researchers still need to complete their research and will find solutions for their problem.

• Tools and documented process can abstract some of this for the researchers to let them focus on the research!
Questions?

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