



Complexities of
Data Sharing with
External
Researchers

HCCA Research
Compliance
Conference
June 9 2022

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Disclosure

*We do not have any relevant
personal, professional or financial relationships
with respect to this educational activity.*

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Objectives

- Understand the background for undue influence concerns and the tension research security measures can create with open scientific collaborations.
- Understand the regulatory and institutional reasons why data security measures are necessary.
- Learn about the complexity of implementing enterprise-wide changes and the intricacies of managing multiple stakeholders to enable a successful change.

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Mass General Brigham Massachusetts General Hospital

*Kelé Piper, MS, CHRC
Director, Research Compliance*



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What do we look like?

- A community of nearly 10,000 people
 - 2,000 principal investigators leading research teams
 - 4,000 scientists and research staff
 - 1,500 research fellows (postdoc)
 - 800-1000 students
 - 1,200+ research administrators and support staff
- Over 30 departments, centers, and institutes
- Over \$1 billion in research revenue/spending
- Over 1.3 million square feet of research space
- Over 2,000 active clinical trials
- Over 500 journal publications per month
- 1/3 of all 3,000 clinicians are also research PIs

Fun Fact!

Over 200 years ago, in 1846, the first operation using ether as an anesthetic was demonstrated, at MGH ushering in the era of painless surgery. On our campus in the Bulfinch Building, it's called the Ether Dome--used today for medical lectures and demonstrations.

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Boston Children's Hospital

*FARIBA HOUMAN, PHD
RESEARCH COMPLIANCE OFFICER*



Where the world comes for answers



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What do we look like?

One of the largest pediatric medical centers in the US

\$423 M funding (FY20); >\$50 M from NIH

~3000 researchers and scientific staff

10 Species/250K research animals

~1500 Sponsored Projects/~450 Clinical trials

>4000 publications/year

40+ companies/2-3 per year



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Tell us about you...

POLL QUESTION #1

What is your role?

- A. Compliance
- B. Clinical Research
- C. Administration
- D. Privacy
- E. IRB/IACUC
- F. Other

POLL QUESTION #2

How long have you been in your role?

- A. Under 5 years
- B. 6-10 years
- C. 10-15 years
- D. A very long time

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Background

UNDERSTAND THE BACKGROUND FOR UNDUE INFLUENCE CONCERNS AND THE TENSION RESEARCH SECURITY MEASURES CAN CREATE WITH OPEN SCIENTIFIC COLLABORATIONS

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Data



Ownership vs. Stewardship

Data Risk Levels

- **Low:** fully de-identified
- **Medium:** contains personal information (PHI or PII); unpublished
- **High:** Medical record, clinical databases

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Data Security Requirements

Congressional bills

Cybersecurity and data integrity (standards and disclosures)

Federal guidance (NSPM33 Implementation)

Funders' requirements (e.g. FDA, DoD, NIH)

Protection laws (HIPAA, GDPR, PIPL, EAR, ITAR)

Confidentiality (intellectual property and protected personal data)

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Case Study—Ground Zero

Xu Chung, a postdoc, is leaving the institution next month, 30 days. In the lab they are completing experiment analysis to begin preparation of a manuscript in which Dr. Chung will be first author. Dr. Chung will be returning to her home country of China. Dr. Chung would like to take her grant-purchased laptop with her and carry the data from her experiments to continue her work but would also like to maintain her hospital email account and access to the departmental share drives and servers. In addition, Dr. Chung would like to take samples and reagents back to China with her so that when she starts in her new lab she can continue the work that she started. Dr. Chung's PI has given her permission to take the data and some of the samples and reagents. The PI has asked Dr. Chung to prepare the samples and reagents for shipping and to upload all of her data into LabArchives.

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Process

UNDERSTAND THE REGULATORY AND INSTITUTIONAL REASONS WHY
DATA SECURITY MEASURES ARE NECESSARY

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Science vs. Institution Challenges

SCIENCE

It is **my** data, I created it.
It is **my** money, I got the grant.
It is **my** equipment, I bought it with my grant.
Manuscript/publication prep
Further analysis
Setting up their own lab
Starting at another institution

INSTITUTION

PI sympathies
Employment laws
Data ownership and stewardship
Risks in data sharing
Contractual agreements
International restrictions

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Information Security
Privacy Office
Research Management/Contracting Office
Research Space & Management Group (RSMG)
Grants Management
Finance

Innovation
IRB/IACUC
Senior Leadership
Export Control Office (Research Compliance)
HR
Global Health

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Who is receiving the data?

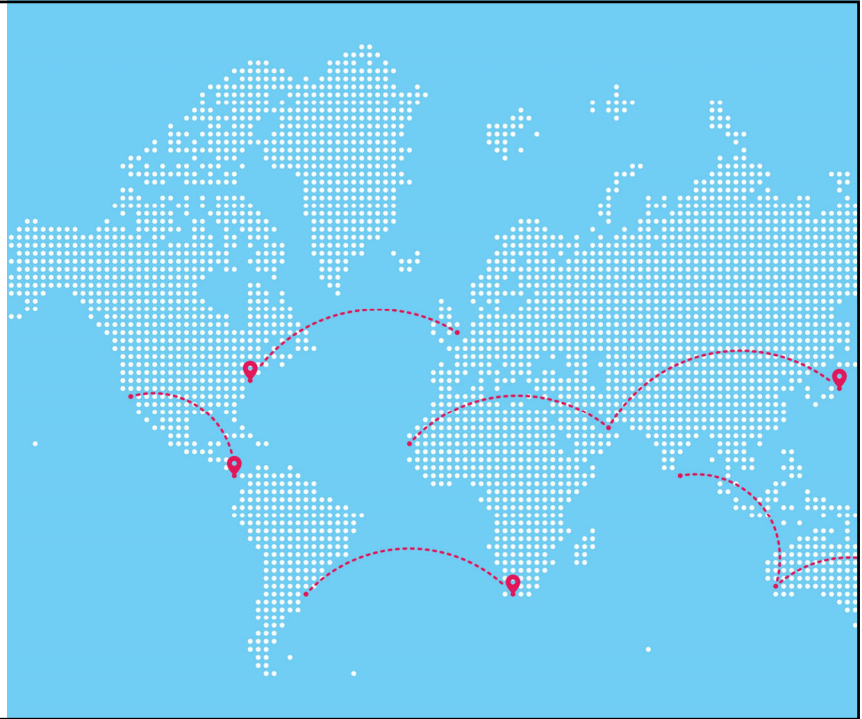
Who are we trying to share data with?

PIs/fellows/postdocs (individually) leaving the institution

Other institutions

Collaborators

Other PIs



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Why are we sharing?

Continuation of the science

Wrapping up/data analysis

Presentations/manuscripts/publications

Transfer of project

Starting a new collaboration

Student/interns—continuation or early start

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What kind of data are we sharing?

Human subject data
De-identified data
Bench/animal data
Films/test data
Intellectual Property
Export controlled
(deemed export)



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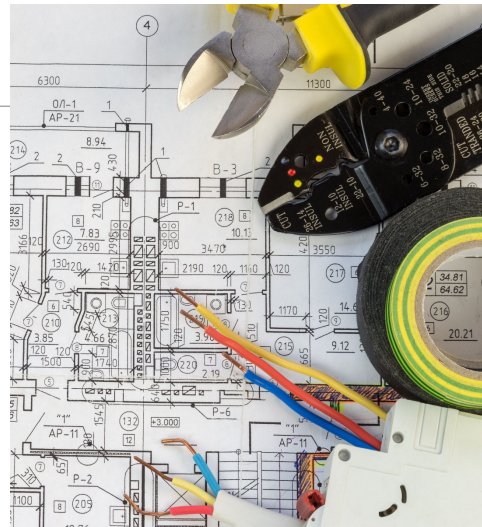
How will they access the data?

Direct institutional access
(VPN, GoToMyPC)
Lab Archives/DropBox
External hard drives/flash
drives, etc.
Email
Laptop

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What are we doing

- Information Security check
- Export control check
- Transfer out packet (paper vs. electronic)
- Agreements
- Non-employees vs. contractual agreements vs. employment extensions
- Types of access
- Sponsor disclosures
- Training and education
- Policies and guidelines



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International Remote Work for Employees

- Broke it down into groups
- Business vs personal
- Policy, laws, and regulations
 - Employment law
 - Tax laws
 - Privacy laws
- Export Controls
- IT Security
- Oversight committee



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Change Management

LEARN ABOUT THE COMPLEXITY OF IMPLEMENTING ENTERPRISE-WIDE CHANGES AND THE INTRICACIES OF MANAGING MULTIPLE STAKEHOLDERS TO ENABLE A SUCCESSFUL CHANGE

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Navigating Culture Change

Successful Change

Workflow

Communication

Infrastructure

<https://medium.com/@sairambandi18/how-change-management-is-inevitable-for-any-organization-74b3b76c51a4>

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Identified the Problems-Now What?

- Understand how the process works
- Form a working group; articulate risks and solutions in a report
- Communicate with leadership
- Work with stakeholders to review impact and drive implementation
- Communicate; beta test, make fixes
- Socialize with training and guidance documents

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Summary of Key Points & Best Practices

Data Access

- Limit to onsite
- Proper agreements
- Minimum necessary
- Share securely
- De-identified
- Honest broker

Training

Policy, SOP, guidelines

Vetting

Joint appointments

Collaborations

Remote access to institutional data poses risk to research data security

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Case Study # 1

Access from China for 2 Years

PI: " When my postdocs leave my lab to launch their own careers as independent investigators, they typically remain involved in the data they were involved with during their time in my lab – in other words, by the time they finish their postdoc, they have not yet completed work on their projects. Thus, they continue to work on data, publish papers, etc. Always, of course, in collaboration with me.

In xx's case, this will be true for the NIH project he has worked on and the Gates Foundation project he has worked on. Note he will not be paid. Rather, he just needs to continue to have access to the same data he's been working on for 3 years.

To prevent him, as well as my other non-US citizen postdocs from doing this would seriously compromise our work, as it would leave things dangling, unfinished. And this, of course, would compromise my chances of additional funding, as I would not be able to demonstrate that I can complete what I start"

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Case Study # 2

Early Access

Request for a Iranian grad student coming from Canada for remote access for one year. Delay due to COVID and visa processing. J1 won't be approved for the remote year requested. Request to share data to have her work remotely. Request for VPN access to look at MRI patient data.

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Case Study # 3

One year access from another U.S. Institution

Keep existing access for one year

XX listed on several IRB protocols and has access to Epic and Peoplesoft

With access to departmental drives and other clinical scans

The objective is to transfer the practical know how from xx as to how to implement and run the high performance software that he wrote for 'specialized instrument'.

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Case Study #4

Medical Record Access for Fellows

From the PI: We have completed this process for our graduating fellows for many years with no issues. “

“Our original data set contained about 150 patients, but we have found about 100 more. Dr. xx has been collecting the data on these patients, and given that they have, complex genetics, and multiple scans over time, there is a lot of data to extract. Direct access to medical records would greatly facilitate completion of the data extraction process. “

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Question?

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Thank you
