LabArchives & Electronic Data Management Requirements

Electronic Data Management Mandate

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Communication about Electronic Lab Notebooks

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From Mass General Research Institute <ResearchInstitute@mgh.harvard.edu>

Electronic Lab Notebooks

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SUBJECT: Electronic Lab Notebooks

...As part of the larger Partners Research Data Management Integrity initiative, we are providing researchers with access to an enterprise-wide electronic lab notebook – LabArchives – free of charge. **Research groups will be required to begin using LabArchives for research recordkeeping and notation no later than October 1, 2019.**
What is LabArchives?

- A secure, cloud-based (AWS Hosted Solution) collaborative platform to organize, document, store, protect, share, collaborate, and publish their research and data.

- A “living repository” – combines the features of collaboration software, wikis, search engines, data storage, publishing and workflow software.

- Web-based - Use from any computer or mobile device; Mobile App

- Advantages:
  - Reduce lost / misplaced / overwritten Data
  - Typed vs Handwritten (illegible) Data
  - Ease in sharing / collaboration
  - Search capabilities
Access LabArchives with Partners Login (SSO)

https://rc.partners.org/eln

http://www.labarchives.com/ >Sign In
Select Site “Partners HealthCare”
Account Creation Clarification

“…Because we plan a one-year lead time, we ask that everyone begin using LabArchives as of October 1, 2018. To help you get started, a personal LabArchives account will be established for each PI of an active research award or Sundry fund by October. You may already have received an email alerting you that a LabArchives account has been established for you and inviting you to log in.”

Everyone can access LabArchives TODAY

- Log in by selecting the site “Partners HealthCare” and use your Partners username and password: https://mynotebook.labarchives.com/login

PIs will be sent an email invite to our shared “Partners HealthCare Research Community Notebook”

- By accessing the notebook, they will be prompted to create an account if they haven’t already

Everyone who logs in to LabArchives will also be granted access to the Research Community Notebook.
**This notebook is available to ALL Partners Researchers.**

- **DO NOT** post identifiable research data that is not public or published!
- **DO** post Templates, Questions, Ideas to share with the Partners Community
- **CREATE NEW** notebooks to manage your research data.**
HOWTO: Create your own Lab Notebook / Space

- Create New Notebooks / Spaces
- Share with your lab, PI

HOWTO: Create your own Lab Notebook:

Navigate to the left Notebook Navigator dropdown and select "Create New Notebook".
Sharing your Notebooks / Space

4 Levels of Access:

• **Owners:** PIs
• **Admins:** Lab Managers, Leads
• **Users:** Scientists, Associates, Assistants
• **Guests:** Collaborators, Non-Partners Users

Determine the best setup for the lab:

– Project-based
– User-based
– Core Facilities / Assay based
Support for LabArchives

**ERIS** supports compliance and security for institution

- Partners Related Questions: edcsupport@partners.org
- Engage ELN Discussion Group: Subscribe
- FAQs: https://rc.partners.org/eln/faqs

**LabArchives** supports end-users and customer service

- Support Resources available:
  - http://labarchives.kayako.com/
  - support@labarchives.com
- Introduction to LabArchives: Every Thursday at 1pm EST - REGISTER
- Introduction to Widgets: To schedule a personalized webinar training on widgets, contact support@labarchives.com
Resources to Support Researchers with Compliance

We’re Hiring!

**Research Applications Services/ELN Program Manager**

**Program Manager (1FTE):** Training Program Development, Policy, Outreach and Communications

**Project Analyst (1FTE)**
- Hands on help to migrate workflows and optimize LabArchives usage
- Use cases will provide insight to our researcher needs
- HOWTO documentation
- Labs will be identified by research types and categories
What if you already have a Data Management System (LIMS, notebook…) in place?

**NEW DELIVERABLE:** The purpose of the Partners Research Data Management Electronic Systems Guidance will be to provide minimal requirements for electronic systems used for the entire Data Life Cycle associated with a research project's Data Management Plan.

**Electronic Systems requirements will include:**
- Intellectual property (IP) protection (Solutions provide assurances in reference to IP litigation)
- Any ELN must have the ability to time, date and user stamp any data entered into the system.
- Audit trails must track all the changes to a record, as well as chain of custody for the data.
- Electronic signatures applied as a result of a controlled workflow must be consistent with Partners' policies and procedures for witnessing experiments.
- Principal Investigators and Lab Manager must access and manage the work
- Compliance and regulatory support: HIPAA and 21 CFR Part 11 Compliance
Additional FAQS!
Is this a storage solution?

Yes, if your files are less than 4GB each
- 4GB limit per file
- Allowed unlimited number of files
- No vendor limit on amount of storage

**Automated Uploads:** File Folder Monitor Plugin

**Coming Soon:**
HOWTO: Link / Reference Data Sources and Files
- How to create actual links?
- What if files move?
What if we have poor/slow wireless access?

Internet Access & Bandwidth
- Web based tool: Bad internet connection?

*Our lab has very poor wireless access and the ports are not active in the majority of outlets, will [this institution] be able to activate these to allow for us to use these systems.*

MGH has a project plan to upgrade and/or install wifi in all research areas over the next 2 years

[edcsupport@partners.org](mailto:edcsupport@partners.org) will help escalate to Research Leadership and PHS IS Network Engineering
What happens when users leave the institution?

LabArchives Data Transfer SOP

Partners’ policies allow a departing researcher (e.g., postdoctoral fellow or PI) to take copies of research data with him or her when leaving a Partners hospital or institution for another employer. When copies or clones of notebooks, pages, sections are created, all original data remain property of Partners. No data are deleted.

HOWTOS:

• Post Doc Leaves (Transfer to PIs)
• PI Leaving Appointing Successor
• PI Leaving and not having a Successor

HOW TO: Create Notebook PDF Copy
HOW TO: Create Notebook HTML Copy
HOW TO: Transfer Ownership of LabArchives Notebooks
Does this apply to ALL research?

Yes, this mandate does impact all researchers.

How does this apply to Clinical Research?
YES, we’ll have specific task force, sessions for Clinical Researchers.

Will this system be replacing REDCap or Dropbox? NO

REDCap and Dropbox, other storage solutions will continue to be supporting solutions. They have different features / functionality that will compliment LabArchives and not be replaced by LabArchives.

We'll provide examples and materials on how different types of studies, projects, sciences, workflows can incorporate LabArchives into your work to improved your documentation and research efficiencies.
How do you transition "old" data into LabArchives?

What resources are available for PIs to import the hundreds of pages of paper notes and records into LabArchives? …If you can help researchers digitize their existing records, then that should make it much, much easier for all researchers to adopt a new, enforced system. …100% of my data is backed up in one or more locations, but unfortunately 0% of my lab notebooks are “backed up” anywhere. One can’t easily “back up” a notebook.

• There is currently no mandate to import past paper lab notebooks or documents into LabArchives or to digitize those notebooks.
• We've received requests and we're working towards a solution
• One option is to: scan paper notes and docs, send to a network file and then have LabArchives file folder monitor automatically upload those entries to a notebook.
Questions?
Research with Digital Health Methods

Overview of Mobile Technology Review Process

Kathi Rossi-Roh
Mobile Application Process Coordinator
What are Digital Health Methods?

**Digital health methods** include collection, transmission and/or dissemination of private or non-private actively or passively collected data or private information using software or technology on mobile or wirelessly communicating devices such as smartphones, free-standing monitors or sensors, or wearable devices that collect information at a point in time or over a period of time.

**This includes:**

- Homegrown smartphone apps or wearables to be potentially marketed broadly, or via partnerships with a third party (software or mobile device creators, software engineer developing digital phenotype software, smartphone app developers).
- Use of marketed and readily available apps or other software in the clinical research context, including wearables (Fitbit, other sensors worn on the body), smartphone apps that passively collect data, installation of monitors that use wireless, Bluetooth or other methods to create information about an individual over time.
- Pervasive data collection using multiple sensors or devices placed in an individual’s or group’s environment.
Digital Health Technologies: In Scope and Out of Scope

In Scope Examples:
• Clinical applications that are part of a research study – proposed or underway/amended
• Mobile applications
• Wearable technology
• Patient facing or PI facing, or both
• Online patient surveys completed on a mobile device

Out of Scope Examples:
• Non clinical applications
• Applications that are not utilized on a mobile device
Digital Health: IRB and Institutional Reviews and Approvals

Issues with Current Process:
• Reviews are needed from multiple stakeholders: IRB, Clinical Trials Office, Ancillary, Information Systems, Information Security, etc
  • Timing of reviews is not a coordinated effort
• Principal Investigators (PIs) and Study Teams may be unaware of all stakeholders – Who to contact and when?
• Different stakeholders require different information about the technologies, vendors and agreements
• PIs/Study teams require assistance in getting technology acquired, configured, and compliant with all Partners policies and stakeholder requirements

Issues have caused:
• Delays in implementation
• Technologies and/or projects not approved
• Risk to network, patients, privacy, etc
Current Processes Navigated by PI

Worst outcome: The idea gets so buried, it does not launch.

Site Innovation Team Support
New Mobile App Process Coordinator (MAPC) Role

• Supported by Academic Research Leadership
• Funded by IRB, CTO and ERIS
• Provides connections between Researchers and relevant Stakeholders
• Tracks progress of IRB / IRB Ancillary Reviewers required approvals in Insight
• Optimizes timing of requests to relevant Partners IS teams
• Docked into IRB to stay apprised of issues/concerns/questions
MAPC: Define Processes and Support the PI

Digital Health Review Process

**Digital Health Review Process**

Research Team

- **HAS AN IDEA Can I do this??**
  - Requires More Info
  - Vendor(s)

- **Applies to IRB**

- **Digital Health Review**
  - **Yes**
    - Identifies Requirements and Partners IS Teams
    - Initiates CTO Review
  - **No**
    - Requires More Info

- **CTO Sends Email**

- **DH Notified**

- **Protocol Submitted**

- **IRB Review**
  - **Defer / Requires Modification / Disapproved**

- **Implement**

- **APPROVED**

- **Work with IS Teams to Implement**

- **IS Does Not Allow / Technology Requires Modification**

**STAKEHOLDERS**

- **Site Support Innovation Teams**
  - Researcher Contacts a Stakeholder
  - Refer to Digital Health
  - IRBDigitalHealth@partners.org
  - https://rc.partners.org/digitalhealth

- **IRB**
  - CTO Review

- **IRB Reviewers / Approvers**

- **Partners IS**
  - Submits IS Requests

- **Ancillary Reviews:**
  - RISO
  - BME

- **EMM: Device Management**
- **Network Eng**
- **Server Teams**
- **PHS eCare**
- **Wireless**
MAPC and Digital Health Review Process: *Just Ask!*

Contact: [IRBDigitalHealth@partners.org](mailto:IRBDigitalHealth@partners.org)

Website: [https://rc.partners.org/digitalhealth](https://rc.partners.org/digitalhealth)
Questions?