PARTNERS HEALTHCARE | FOUNDED BY BRIGHAM AND WOMEN'S HOSPITAL AND MASSACHUSETTS GENERAL HOSPITAL

Title:	Partners Electronic Lab Notebook (ELN) Policy
Department:	Partners Research Compliance
Policy Type:	☐X Partners System-wide ☐ Partners System-wide Template ☐ Partners HealthCare ☐ Partners HealthCare Departmental ☐ Institution
Applies to:	All Partners HealthCare Entities, Employees, and Agents (Partners) who are involved in the performance, oversight and administration of research
Approved by:	Anne Klibanski, MD, PHS Chief Academic Officer and Interim CEO Paul Anderson, MD, PhD, BWH CAO & SVP for Research Harry Orf, PhD, MGH SVP for Research Kerry Ressler, MD, PhD, McLean Chief Scientific Officer Shawn Murphy, MD, PhD, PHS Chief Research Information Officer Robert Damiano, PHS VP Compliance, Audit & Business Integrity
Original Approval Date:	March 17, 2019
Original Effective Date:	May 1, 2019
Revision Approval Date(s):	NA
Current Revision Effective Date:	NA
Next Review Date:	May 1, 2022
Contact Person:	Electronic Lab Notebook (ELN) Project Manager

KEYWORDS:

Electronic Lab Notebook, ELN, Information Security, Research Data, Research Information

PURPOSE:

The purpose of this policy is to set forth Partners-wide minimum requirements, standards, and implementation schedule for Electronic Lab Notebooks (ELN) and related systems.

DEFINITIONS:

Research Data are any, and all, electronic or paper data and information created or collected in the process of performing research.

Data Integrity is a measure of how accurately and reliably Research Data reflect the study's research activities.

Data Life Cycle refers to the time-period from collection to destruction of Research Data associated with a research project. This includes analysis, use, sharing, storage, and archiving.

Data Management Plan ("DMP") is a written description of how Research Data will be collected, maintained, shared, retained, and destroyed throughout a research project.

Principal Investigator: The Principal Investigator (PI) is the individual designated by the Partners hospital or institute with the appropriate level of authority and responsibility to direct a research or training award or program supported by an external sponsor or Sundry fund. This individual leads the design, conduct and reporting of the project and has primary responsibility for compliance with scientific, technical, administrative, and financial requirements

Active Research Project: Award funded by an external sponsor or Sundry fund that is ongoing as of the effective date of this policy

POLICY STATEMENT:

Principal Investigators (PI) of Partners HealthCare (Partners) active research projects must transition from basic data documentation and management methods, e.g., use of MS Word, Excel without controls for auditing and tracking changes, paper laboratory notebooks, and paper processes, to digital technologies/electronic systems, i.e., Electronic Lab Notebooks or Research Notebooks (ELN), in accordance with the implementation schedule listed below. Transition to electronic systems is required to meet regulatory and institutional compliance requirements, mitigate security risks, maintain data integrity, and protect intellectual property.

In addition to documenting Research Data in the ELN, PIs are also responsible for documenting other record keeping activities in the ELN. These include, but are not limited to, planning and protocol descriptions, data manipulation and analytical procedures, important communications and decisions about the research.

LabArchives is the ELN system Partners has established for researchers to meet these requirements. . PIs are required to establish a LabArchives account in their name and create notebooks and designate notebook access for their research staff.

EXCEPTIONS:

As described below, laboratories, research groups and departments with well-established electronic lab or data management systems, processes, and ELNs may request approval to continue with their system(s) in lieu of LabArchives provided their system(s) meet the minimum standards outlined below. All requests for exceptions must be submitted to the ELN Support Team and approved by the ELN Oversight Committee (consisting of Partners Chief Academic Officer, BWH SVP for Research, MGH SVP for Research, McLean Chief Scientific Officer, and Partners Chief Research Information Officer.)

This Policy does not apply to

- Clinical research projects that utilize electronic lab or data management systems, processes, and ELNs that are 21 CFR Part 11 compliant, or
- Sponsor-initiated clinical trials that utilize sponsor systems and processes.

RESEARCH DATA ELECTRONIC SYSTEMS/ELN MINIMUM STANDARDS:

1) The ELN must be compliant with all Partners Enterprise Information Security Policies, Standards, and Procedures.

2) The ELN must be compliant with applicable regulatory and legal requirements evaluated and applied where appropriate including, but not limited to:

- Health Insurance Portability and Accountability Act (HIPAA);
- Mass General Law, Chapter 93H (M.G.L.c.93H); and
- EU General Data Protection Requirement (GDPR) if the Research Data include personal data collected in the EU, and the research is operating under a contract or research agreement with GDPR terms.

3) ELN Systems that include signing and witnessing of electronic records with electronic signatures must also comply with Title 21 of the Code of Federal Regulations (21 CFR Part 11.)

4) The ELN must include Data Integrity Controls for the entire Data Life Cycle. These include, but are not limited to:

- Date time, user, and action logs of any modification to Research Data;
- Inability to delete data or record keeping activities without appropriate deletion logs;
- Control of ELN access and user management by PI and/or Lab Manager or designee
- Documentation of Research Data chain of custody (i.e. Ownership, PI Transfer In/Out)
- Logs that record access to information or data sharing activities.

EXCEPTIONS: EXEMPTION/VARIANCE REQUEST PROCESS

- Research ELN Exemption/Variance requests will be granted if the review process determines that the laboratory, research group or department:
    - Cannot use LabArchives due to legitimate technical or documented business constraints; or
    - Has sufficiently demonstrated maintenance of data integrity by implementing systems or processes that meet the Research Data Electronic Systems/ELN Minimum Standards
- Approval of Exemption/Variance requests is limited to the ELN Oversight Committee or designee(s).
- PIs may request an Exemption/Variance by contacting the ELN Support Team
    - **Exemption** to the policy will be granted to systems for the duration of the laboratory, research group or department's active projects, where processes and systems are established and consistent. Exemptions will be reviewed periodically by the ELN Support Team, e.g., on an annual basis or during award renewal cycles.
    - **Variance** requests will be granted for a maximum of one year. The PI of an approved Variance is responsible for complying with all approval requirements, including resubmission prior to variance expiration if an extension is required. Systems or processes approved under a variance may not be modified without prior approval by the ELN Oversight Committee.

IMPLEMENTATION SCHEDULE AND COMPLIANCE:

Individuals with PI status are required to transition to electronic data management systems/ELNs or to secure approval of an exception in accordance with the following implementation schedule:

Hospital/Institute	Establish PI LabArchives Account	Approval of Exception	Full LabArchives Implementation
BWH	10/1/19	9/15/19	10/1/19
MGH	10/1/19	9/15//19	10/1/19
McLean	10/1/19	12/10/19	1/1/20
MEE	10/1/19	12/10/19	1/1/20
Spaulding	10/1/19	12/10/19	1/1/20
IHP	10/1/19	12/10/19	1/1/20

Individuals appointed to a Partners hospital with PI status or who are promoted to PI status after the full LabArchives implementation date of their hospital/institute must begin to use electronic data management systems/ELNs immediately upon assuming their Partners position and embarking on their research.

To monitor compliance with this Policy, in CY 2020, Hospital Research Compliance or Hospital Corporate Compliance staff will work with the ELN Project Manager or designee and Partners Research Compliance to confirm that all PIs have transitioned to LabArchives or have been approved for an exemption. Partners reserves the right to conduct additional reviews or audits should the need arise.

Failure to comply with this Policy will be reported to the hospital's SVP for Research or equivalent position for further action which may include loss of PI privileges or other sanctions.

OTHER APPLICABLE PARTNERS HEALTHCARE POLICIES:

Partners Enterprise Information Security Policies, Standards, and Procedures
Research Management Policies:

- Intellectual Property Policy for Partners Affiliated Hospitals and Institutions
- Research Information Ownership Policy

REFERENCE:

Partners Research Data Management Requirements

DEVELOPMENT AND CONSULTATION

(Mandatory) Enter key groups or leaders who were consulted and approved policy. This section helps to guide subsequent reviews of substantive policy revisions.

Reviewed by:	Original Review Date:	Revision Approval Dates:
Partners Research Compliance Committee	12/14/18	
BWH Research IT Advisory Group	12/12/18	
MGH Research IT Advisory Group	1/3/19	
McLean Research IT Advisory Group	1/29/19	
MEE Research Steering Committee	11/15/18	
MGH Committee on Fundamental Research	2/12/19	
Spaulding Research Faculty	2/8/19	
IHP Assoc Provost/Research	2/15/19	
Chief Research Computing Officer/S. Murphy	3/4/19	
CAO/A. Klibanski	3/11/19	
MGH SVP/H. Orf	3/8/19	
BWH SVP/P.Anderson	3/15/19	
McLean CSO/K.Ressler	3/8/19	
PHS/VP Compliance/R. Damiano	3/17/19	