

**Full-Length Paper****Finding Connections in Policies Covering Electronic Laboratory Notebook Retention and Transferal**

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Abstract

Objective: As electronic laboratory notebook (ELN) capabilities continue to expand, more researchers are turning to this digital format. The University of Massachusetts Medical School developed new guidelines to outline the retention and transferal of ELNs. How do other universities approach the retention and transferal of laboratory notebooks, including ELNs?

Methods: The websites of 25 universities were searched for policies or guidelines on laboratory notebook retention and transferal. A textual analysis of the policies was performed to find common themes.

Results: Information on the retention and transferal of laboratory notebooks was found in record retention and research data policies/guidelines. Of the 25 institutional websites searched, 16 policies/guidelines on research notebook retention were found and 10 institutions had policies/guidelines on transferring research notebooks when a researcher leaves the university. Only one policy had a retention recommendation for storage location specific to electronic media,

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Abstract Continued

including laboratory notebooks, that did not apply to its paper counterparts; the remaining policies either explicitly include multiple forms and media or do not mention multiple formats for research records at all. The minimum number of years of retention for research notebooks ranged from immediately after report completion to seven years after completing the research with the possibility of extension depending on a wide range of external requirements. Most research notebook transferal policies and guidelines required associated researchers and students to request permission from their principal investigator (PI) before taking a copy of the notebook. Most institutions with policies also seek to retain access to research notebooks when a PI leaves an institution to protect intellectual property and respond to any cases of scientific misconduct or conflict of interest.

Conclusions: Other universities have a range of approaches for the retention and transferal of laboratory notebooks, but most provide the same recommendations for both electronic and physical laboratory notebooks in their research data or record retention policies/guidelines.

Introduction

Laboratory notebooks play an important role in research. Not only do they help a researcher organize and track their experiments (Bird, Willoughby, and Frey 2013), they also serve as support for patents (Bird, Willoughby, and Frey 2013; Nickla and Boehm 2011; Heines 2012), evidence of following regulations (Bird, Willoughby, and Frey 2013), and protection against allegations of scientific misconduct (Nickla and Boehm 2011). The advent of electronic laboratory notebooks (ELNs) has increased the functionality of the humble notebook to include integrations with laboratory equipment and software to automatically capture data (Bogdan and Flowers 2014; Dunie 2017; Machina and Wild 2013) and enable collaboration with other researchers who may be on the other side of the globe (Dunie 2017). The increasing benefits of the electronic format have spurred a growing number of researchers to go digital.

Laboratory notebooks are usually considered property of the institution (Nickla and Boehm 2011) and the institution has a vested interest in retaining access to the notebook once a researcher leaves for another institution or a principal investigator (PI) retires. But space, even digital space, is not infinite and institutions generally keep track of when documents can be disposed through record retention schedules. The advantages of digital space, being cheaper and conducive to collaboration, may warrant different retention for electronic documents such as ELNs. Notebook policies have been used to ensure “timely and accurate signing, dating, and witnessing of each scientist’s laboratory notebook” (Kowalski et al. 2002) at research institutions. Policies can also be used to mandate the retention and transferal of ELNs.

At the University of Massachusetts Medical School (UMMS), there is an existing retention policy for paper laboratory notebooks, but it does not encapsulate their electronic counterparts. After receiving questions about what happens to the electronic notebooks once a researcher leaves UMMS, separate retention and transferal guidelines for ELNs were developed through a collaboration between Information Technology and the Library (Appendix A). The guidelines specify that ELNs are the property of UMMS, PIs are responsible for the ELNs in their lab, associated researchers and students leaving UMMS must request permission from their PI before taking a copy of an ELN, and, while a PI may take a copy of the ELN when they leave the institution, they must leave the original at UMMS.

While the guidelines were created to meet the needs of UMMS, there were likely some factors of laboratory notebook retention and transfer that we had not considered. Therefore, we turned to similar universities to explore how their policies address the retention and transferal of laboratory notebooks and whether ELNs were specifically addressed.

Methods

The websites of the other University of Massachusetts campuses (4) and peer

institutions to UMMS (21) were searched for policies or guidelines on laboratory notebook retention and transferal. The peer institutions were determined by the administration of UMMS for comparison during reviews and planning. This list of institutions includes local medical schools, medical schools of similar size and, as with UMMS, independent medical schools that are also part of a larger university system. The list also includes aspirational schools which are more highly ranked in areas where UMMS would like to improve. Eight private institutions (Boston University; Brown University; Dartmouth College; Harvard University; Johns Hopkins University; Tufts University; Washington University in St. Louis; and Yale University) and 17 public institutions (State University of New York, Stony Brook; University of Alabama at Birmingham; University of California, San Francisco; University of Iowa; University of Maryland - Baltimore; University of Massachusetts Amherst; University of Massachusetts Boston; University of Massachusetts Dartmouth; University of Massachusetts Lowell; University of Michigan - Ann Arbor; University of North Carolina at Chapel Hill; University of Pennsylvania; University of Pittsburgh - Pittsburgh; University of Texas, SW; University of Vermont; University of Washington - Seattle; and University of Wisconsin - Madison) were surveyed. A textual analysis of the policies was performed to determine whether they covered electronic as well as paper notebooks, the minimum years of retention recommended or mandated, and the process for transferring lab notebooks when a researcher leaves an institution. Recognizing that some institutional policies and guidelines are only available to members of that institution, the presence of a policy on laboratory notebook retention or transferal was marked as unknown when no relevant policy was found on the institution's public website. If the author was able to confirm with a member of the institution that they do not have any policies or guidelines on laboratory notebook retention or transferal, the institution was then marked as not having one. Additionally, it was unclear if the retention and transferal information found on some institutional websites and policies about laboratory equipment and/or data pertained to laboratory notebooks. In these cases, the presence of a policy on laboratory notebook retention or transferal was marked as unclear. Policies were differentiated from guidelines by the presence of the term policy in the title of the document. Documents attached to policies, such as record retention schedules, were also considered part of the larger policy.

Results

Of the 25 institutional websites searched, a policy or guideline containing information on research notebook retention was found for 16 institutions (Table 1). None of the 16 institutions had a separate retention policy specific to research lab notebooks; seven had this information as part of their retention schedules and nine had it as part of their research data policies/guidelines. Nine of the 16 policies/guidelines included information on transferring research notebooks when a researcher leaves the university with one institution having separate guidelines for offboarding PIs. A full list of the policies/guidelines and their web addresses can be found in Appendix B.

The only institution to have separate requirements or recommendations for the retention of electronic notebooks and their paper counterparts is Boston University (2018). Boston University’s (2018) “Scientific Research Data Policy” specifies that physical records are normally retained “in the unit where they are produced” and electronic records “should be maintained in University-supported storage or systems.” While Boston University outlines different storage strategies for electronic and physical records, none of the policies found had any specific requirements or recommendations about the length of retention or transferal of electronic notebooks that differ from their physical counterparts. Most policies/guidelines were explicit in saying the policies applied to records and data, including laboratory notebooks, regardless of form or media (Dartmouth College 2019; Harvard University 2017; Johns Hopkins University 2008; University of Alabama at Birmingham 2013; University Archives and Records Management Services, Wilson Special Collections Library, The University of North Carolina at Chapel Hill 2019; University of Maryland – Baltimore 2017; University of Pennsylvania 2010; 2011; University of Pittsburgh 2009; The University of Vermont 2018; University of Washington 2019a; University of Wisconsin - Madison 2019; Yale University 2018). A couple of policies do not mention electronic or multiple forms of media (State University of New York, Stony Brook 2019; University of Massachusetts Boston 2016). The University of Iowa’s (2019) “Institutional Data Policy” falls under the IT Security and Policy Office and has a focus on electronic information.

The institutions were primarily public universities (68%) but the percentage of public and private institutions who had policies or guidelines on laboratory notebook retention was almost equal (65% of public and 63% of private). A larger percentage of private universities (63%) had policies/guidelines on the transferal of laboratory notebooks as compared to 29% of public universities.

Table 1: Number of institutions with a policy or guidelines on the retention of research notebooks and/or a policy or guidelines on the transferal of research notebooks for when a researcher leaves.

	Policy	Guidelines	Neither policies nor guidelines	Unclear/Unknown
Number of institutions which mention retention of research notebooks in...	13	3	5	4
Number of institutions which mention transferal of research notebooks once researcher leaves in...	7	3	7	8

The minimum number of years of retention for research notebooks ranged from “until the completion of the final report” (University of Alabama at Birmingham 2017) to 7 years after completion of research with the possibility of extension depending on external requirements (Table 2). The ranges for minimum years of retention did not differ for private and public universities.

Table 2: Minimum years of retention required for laboratory notebooks after completion of research found in institutional policies and guidelines.

Minimum years of retention required after completion of research	Number of institutions (n=16)
7 years	5
6 years	1
5 years	2
3 years	4
“Until the completion of the final report”	1
“An adequate period of time”, or to satisfy state/federal/sponsor regulations	3

There are a range of external factors mentioned in the policies and guidelines that extend or change the retention period (Table 3). Two policies extended the retention period from 3 years to 6 years when personal health information was contained in the research (State University of New York, Stony Brook 2019; University Archives and Records Management Services, Wilson Special Collections Library, The University of North Carolina at Chapel Hill 2019). Two guidelines recommend a longer retention period when special populations such as children and individuals with mental incapacity/illness are research subjects (Harvard University 2017; University of Pittsburgh 2009). Harvard (2017) recommends retaining research notebooks from research involving children for 7 years after the child has reached the age of majority, or 7 years after any mental incapacity has been removed from the study’s subject. Harvard makes this recommendation because during “minority and/or periods of mental incapacity, statutes of limitations are commonly tolled, allowing these persons, when they attain majority or capacity to file any legal claims for a period of up to six years after attaining majority or capacity” (Harvard University 2017). The University of Pittsburgh’s (2009) guidelines have a similar recommendation of retaining records for research studies involving children until the child reaches the age of 23. Students and postdoctoral associates were also taken into account in some of the policies/guidelines by extending the retention period start date to when the student graduates, completes training, or abandons the work (Harvard University 2017; University of Wisconsin - Madison 2019).

Table 3: External factors that extend or change a laboratory notebook retention period found in institutional policies and guidelines.

External factors that extend or change a laboratory notebook retention period	Number of institutions (n=16)	Length of extension or change to laboratory notebook retention period
Sponsor requirements	6	Not provided.
Research involving FDA regulated articles	4	2 years post-approval of marketing application or 2 years after discontinued investigation for a drug and a similar retention for FDA-regulated devices (State University of New York, Stony Brook 2019; University of Pittsburgh 2009; Yale University 2018).
Patents and intellectual property requirements	3	20 years for patents (University of Alabama at Birmingham 2017).
Research involving personal health information	2	6 years total retention (State University of New York, Stony Brook 2019; University Archives and Records Management Services, Wilson Special Collections Library, The University of North Carolina at Chapel Hill 2019).
Research involving research subjects from special populations such as children and individuals with mental incapacity/ illness	2	7 years after child has reached majority or incapacity/illness has been removed (Harvard University 2017). Child reaches age of 23 (University of Pittsburgh 2009).
Research is part of student or postdoctoral research still in progress	2	Retention period starts when student/postdoc graduates, completes training, or abandons the work (Harvard University 2017; University of Wisconsin - Madison 2019).
Allegations of scientific misconduct or conflict of interest	1	Retention period starts when the issue is resolved (University of Wisconsin - Madison 2019).
Archival or historical significance	1	Not provided.

Some extensions are to compensate for federal funding or regulations. The retention period for research involving United States Food and Drug Administration (FDA) regulated articles is mentioned in four policies/guidelines as a reminder of the retention period set out in the Code of Federal Regulations: two years post-approval of marketing application or two years after discontinued investigation for a drug and a similar retention for FDA-regulated devices (Harvard University 2017; State University of New York, Stony Brook 2019; University of Pittsburgh 2009; Yale University 2018). Six policies/guidelines acknowledge that retention periods need to be adjusted to comply with sponsor requirements (Dartmouth College 2019; Harvard University 2017; State University of New York, Stony Brook 2019; The University of Vermont 2019; University of Alabama at Birmingham 2017; University of Wisconsin - Madison 2019). Retaining research notebooks for patents and intellectual property requirements is a component of three policies/guidelines (Harvard University 2017; University of Alabama at Birmingham 2017; University of Wisconsin - Madison 2019). Of the three policies/ guidelines, University of Alabama at Birmingham (2017) has the only policy specifying that research records need to be retained to meet the “federal regulation for patents of 20 years or even longer.” The University of Wisconsin - Madison’s (2019) policy acknowledges that research notebooks may also need to be retained longer when there are allegations of scientific misconduct or conflict of interest, and in these cases the retention period would start when the issue is resolved. One policy also takes into account the need to extend a retention period if a research notebook has archival or historical significance (Yale University 2018).

Table 4: Institutional requirements for transferring laboratory notebooks found in institutional policies and guidelines.

Institutional requirements for transferring laboratory notebooks	Number of institutions (n=10)
Students and associated researchers must seek the permission of their PI to make copies of the notebook	9
Researcher may take original notebooks but must provide access to institution upon request	5
Signed agreement required with the new institution	3
Originals must be kept at the institution	1
Researcher must seek special approval if the Institutional Review Board is involved with the research	1
Process of transferal is up to each School to develop	1

The 10 institutions that had research notebook transferal policies or guidelines varied in their approach to transferal (Table 4). The one similarity between the majority of institutions (9/10) is the requirement for associated researchers and students to seek permission from their PI to make copies of the notebook when leaving the institution (Boston University 2018; Dartmouth College 2019; Harvard University 2017; Johns Hopkins University 2008; University of Maryland - Baltimore 2017; University of Pittsburgh 2009; University of Washington 2019b; University of Wisconsin - Madison 2019; Yale University 2018). Six of the 10 policies included requirements that allow the institution to maintain access to the research notebook after a researcher has left in one of two ways (Boston University 2018; Dartmouth College 2019; Johns Hopkins University 2008; University of Maryland - Baltimore 2017; University of Pennsylvania 2010; University of Wisconsin - Madison 2019): by keeping the originals at the institution (University of Maryland - Baltimore 2017) or, if researchers are allowed to take originals, they must provide access to the institution upon request (Boston University 2018; Dartmouth College 2019; Johns Hopkins University 2008; University of Pennsylvania 2010; University of Wisconsin - Madison 2019). Researchers are also required to go through some extra steps when transferring their research notebook at some institutions. Some require a signed agreement with the new institution (Boston University 2018; University of Washington 2019b; University of Wisconsin - Madison 2019) and, if the Institutional Review Board is involved with the research, the researcher must seek special approval to transfer or copy the notebook (University of Wisconsin - Madison 2019). Harvard University (2017) took a different approach and, rather than having an institutional policy on research notebook transferal, has left it to schools or department to develop their own process.

Discussion

The institutions surveyed had a range of approaches to laboratory notebook retention and transferal. Whether the university was public or private did not seem to have a large impact on whether the institution had a policy on laboratory notebook retention. It appears there is a difference in the percentage of public vs. private universities that have a policy on laboratory notebook transferal, but the sample size is too small to have statistical confidence in this conclusion.

Only one policy had a recommendation specific to electronic media, including laboratory notebooks, that did not apply to its paper counterparts and that recommendation highlighted the different storage needs for electronic and physical media. The remaining policies either explicitly include multiple forms and media or do not mention multiple formats for research records at all. With the exceptions of Johns Hopkins University, the University of Pennsylvania, and the University of Pittsburgh, all of the policies have been edited in the last 5 years and therefore adjustments may have been made in the most recent edit to take ELNs into account. It is also possible that ELNs have not risen as an institutional concern. While UMMS has an institutional subscription to LabArchives, electronic laboratory notebook software, other institutions may not have an institutional subscription to

ELN software.

When the number of years for minimum retention was given in the policies/guidelines, it was between 3-7 years and thus provides a good starting point for any institution looking to create a specific timeline. Within this range of retention periods, a retention period of 6-7 years after the completion of a study was the general consensus for human subjects research. For medical institutions who primarily perform human subjects research, a 7-year retention period for all research makes sense. The elongated retention for human subjects takes into account that the subjects themselves might be interested in the research and provides evidence in case of negative effects of research on the human subjects. University of Alabama at Birmingham's (2017) policy recommended 20 years or longer when retaining research notebooks for patents and Heines (2012) and Nickla and Boehm (2011) recommend a similar retention period of approximately 25-30 years. Instead of giving a specific number of years to extend the retention period, some retention period extensions, such as for studies involving children and vulnerable populations, research involving active students/postdoctoral associates, and cases of scientific misconduct or conflict of interest, changed the start of the retention period to account for the variability in these scenarios. Some policies also remind researchers of their other obligations to retain their notebooks for government agencies and sponsors and rely on researchers to be familiar with the relevant policies. Staying up-to-date on these policies is one way that librarians can help researchers at their institution. The substantial number of policies which mention sponsors and the FDA as reasons to extend the retention period also provide a glimpse at the impact sponsors and government entities can have on data reuse, as increased retention periods also increase access. While no retention period was given for laboratory notebooks with archival/historical significance, the assumption is that they would be retained in perpetuity.

Most policies and guidelines on research notebook transferal required associated researchers and students to request permission from their PI before taking a copy of the notebook. Most institutions with policies also seek to retain access to research notebooks when a PI leaves an institution to protect intellectual property and respond to any cases of scientific misconduct or conflict of interest. Remarkably, few universities had policies or guidelines on the transferal of laboratory notebooks when a researcher leaves the institution. This finding was particularly surprising since ELNs were meant to help prevent notebooks from "walking", which was rampant amongst their paper predecessors (Dunie 2017). Even with ELNs, if there is no policy or procedure in place for transferring the notebook when a researcher leaves, the institution is opening itself to liability if the researcher is accused of scientific misconduct or a patent is challenged and the institution cannot produce the notebook(s). Without a procedure or a policy in place, the institution can lose a piece of its physical or digital manifestation of knowledge and experience as the notebook walks out the door. With so many regulations to comply with, institutions can also assist researchers by including research notebooks in their offboarding procedures.

The results of this survey have confirmed that the current UMMS ELN guidelines are consistent with peer institutions, but the UMMS record retention schedule is unique in that it only pertains to paper laboratory notebooks. A retention period was not outlined in the original guidelines, so a seven-year retention period with extensions for FDA regulated articles, studies involving children and vulnerable groups, patent requirements, research involving active students/postdoctoral associates, archival/historical significance, or sponsor requirements, has been recommended to UMMS administration. The Library is also working with Information Technology to develop a centralized LabArchives account to become the owner of LabArchives notebooks being retained by the University when a PI leaves. Once the retention period recommendation is approved by administration, the Electronic Lab Notebook Ownership and User Access guidelines will be updated and accessible to the entire UMMS community, not only those that use LabArchives. We are also trying to align the ELN guidelines with existing protocols and policies, such as working with the Office of Sponsored Programs to add laboratory notebooks to the grant closeout checklist and developing an archiving process where the Office of Technology can determine if any laboratory notebooks contain patent information. A research data policy for UMMS would be ideal and the guidelines and measures being put in place will help guide researchers and staff until such a policy can be developed. Although the recommendations made for UMMS cannot be generalized for all institutions, hopefully the information found in this survey will provide a starting point for other institutions hoping to provide guidance on laboratory notebook retention and transferal within their own policies. This study looked at a very small, biased sample of institutions that were comparable to University of Massachusetts Medical School, which is a biomedically-focused university in New England with approximately 3400 faculty and 1150 students. Thus, the sample is skewed towards medical schools in New England and those of similar size across the United States. The sampling method was chosen under the belief that policies of similar institutions would be the most relevant to UMMS. The study was also limited to policies that were publicly available on institutional websites so some institutions may have a relevant policy that is not publicly available.

Since this was a limited study, a larger number of institutions should be surveyed to see if the themes found in this study hold true for more institutions. Another open question is whether researchers are aware of institutional policies and whether there are clear procedures in place to carry out the policy. Further research is needed to get a better understanding of the policy's uptake at an institutional level and to determine whether it is effective or not. It is not clear how institutions are managing the storage of electronic notebooks once researchers leave in terms of the chosen electronic storage solution and the authority on campus responsible for the storage and retrieval of the archived notebooks. These are questions open for future research.

Conclusions

Laboratory notebooks play an important role in science and, like most aspects of

science, they have also gone digital. What happens to the digital lab notebooks is a matter of concern for both researchers and administration, and as such, clear policies should be provided. In this study, the policies and guidelines of medical schools and universities similar to UMMS in size and scope were examined. The policies found had a range of timeframes for how long a notebook should be retained and different approaches to laboratory notebook transferal. For many institutions, a seven-year retention period seems to be the prevailing norm to account for the significant number of human studies performed. The policies concerning transferal of laboratory notebooks reinforce the existing research ownership structure within the institution, with students and associated researchers requiring permission from PIs to create copies of notebooks and institutions retaining access to notebooks once a PI leaves the institution. There were also institutions without policies or guidelines on laboratory notebook retention and transferal at the time of this study. With so many regulations to comply with, institutions can assist researchers by including research notebooks in offboarding procedures and by reviewing retention and transferal policies to ensure they apply to electronic laboratory notebooks as well.

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Disclosures

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Data Availability

Data available as supplementary file at <https://doi.org/10.7191/jeslib.2020.1190> under "Additional Files."

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