



## RETENTION AND MAINTENANCE OF RESEARCH RECORDS AND DATA: PRINCIPLES AND FREQUENTLY ASKED QUESTIONS (“FAQS”)

At the direction of Provost Steve Hyman during the 2010-2011 academic year, the Sponsored Administration Leadership Committee (“SALC”), in collaboration with faculty and administrators at several Schools, the University Chief Information Officer, the University Archives, the Office of the General Counsel and the Office of Technology Development, outlined a set of basic principles to guide the retention and maintenance of research records by Harvard faculty and staff. In June 2011, outgoing Provost Steve Hyman and incoming Provost Alan Garber adopted these Principles and appointed Anne Margulies, University CIO, and Karen Emmons, HSPH Associate Dean for Research, to chair an ad hoc committee comprised of faculty and administrators to expand upon these principles and to prepare guidance applying these principles to the wide range and various methods of research at Harvard.

The Committee developed the following guidance in the form of Retention and Maintenance of Research Records and Data Frequently Asked Questions (“FAQS”), organized by Principle. The answers below establish the minimum University requirements for research records and data retention. Each School must appoint a representative responsible for research records and data retention issues, consider discipline-specific issues and provide further guidance beyond these minimal requirements, consistent with best practices of the disciplines contained within that School. The Provost’s Office is charged with assuring that each School appoints such a representative and develops discipline-specific additional guidance for each School that will be consistent with the Principles and this guidance. Once a year, all School representatives, the Provost’s Office and the consultative group described above will meet to discuss outstanding issues and best practices that can be shared across all Schools.

**Principle 1: Harvard researchers and staff should have systems or practices for maintaining the essential Research Records that they create in order to be able reasonably to support research findings, justify the uses of research funds and resources, and protect any resulting intellectual property. In determining which records are essential, Harvard researchers and staff should use prudence and reasoned judgment and may seek to refer to the prevailing standards in their relevant academic or professional disciplines. In general, researchers and staff should keep those records that will document research findings and justify the uses of research funds and other resources.**

**1. Why must Harvard Researchers have systems and procedures for maintaining essential Research Records?**

Systems and procedures for maintaining essential Research Records are necessary to protect researchers, students, trainees and the University by ensuring accountability in sponsored research projects and research integrity in all research conducted at, or under the auspices of, the University. Researchers have certain obligations to record, maintain and retain research records, and to make those records available for grant monitoring and auditing purposes, as well as to enable investigators and the institution to respond to questions of research integrity and stewardship. See, e.g., OMB Circular A-110, 2 CFR 215, 42 CFR 93.106(b). The University and its researchers are accountable for ensuring the integrity of, and access to, research data and materials and documents, materials and information that relate to the administration and financial management of research, reporting of research results, sponsored award applications, and human research records. This responsibility continues even after researchers who originally collected those data and materials have left the University.

**2. Do the Principles governing the retention and maintenance of Research Records apply to research conducted with Harvard’s own funds?**

Yes. Harvard’s legal responsibilities with respect to access and retention of data generated by research extend to research conducted with Harvard’s own funds, as well as to research conducted with funds received by Harvard from federal or other sources. These responsibilities include, but are not limited to:

- Complying with federal and University requirements regarding the conduct of research, such as ensuring the appropriate use of animals, human subjects, recombinant DNA, radioactive materials, “select agents,” etc.;
- Ensuring that research is conducted responsibly;
- Adhering to the terms and fulfilling any applicable scopes of work of project agreements and subcontracts or subawards;
- Protecting the rights of students, postdoctoral scholars, and staff, including, but not limited to, their rights to access data from research in which they participated;
- Securing intellectual property rights; and
- Making research records, including data and materials, available to colleagues, administrators, funders or others who have a legitimate need to examine the propriety of expenditures, or to examine data in order to verify their accuracy and/or to review or replicate research findings.

**3. Who Must Comply with the Retention and Maintenance of Research Records Principles?**

All Principal Investigators (“PIs”) and all Harvard University faculty, other academic appointees, staff, students, visitors and any other individuals involved in the design, conduct, reporting, or financial and other administration of research at Harvard University

Schools, local units, and University-wide initiatives must comply with the Principles and attendant guidance contained in these FAQs.

#### **4. What are Research Records?**

Research Records include Research Data and Materials (defined below), as well as documents, materials and information that relate to: administrative, financial, and human resource management of research, reporting of research results, and sponsored award applications. This includes, but is not limited to, financial, administrative, cost or pricing, or other management information that has been gathered or used to apply for or support specific research activities, such as grant proposals, progress reports, and communications with funders. Forms in which Research Records may appear can differ among and across academic disciplines, and can include data in electronic form, such as electronic mail and budget spreadsheets.

#### **5. What are Research Data and Materials?**

Research Data and Materials include recorded, tangible, or intangible research information, regardless of form or the media on which it may be recorded, that is created or collected in the process of performing research, whether supported by University resources or by external funders. Research Data and Materials include, but are not limited to, computer software (computer programs, computer databases, and documentation thereof), materials such as unmodified and modified biological specimens, new or modified chemical entities, laboratory notebooks, notes of any type, materials submitted to and/or approved by IRB, IACUC, or other research oversight committees (e.g., applications, outreach/advertising materials, consent forms, survey routines/questionnaires and debriefing scripts), photographs, films, audio recordings, digital images, original or modified biological and environmental samples, gels, spectra, cell lines, reagents, protocols, algorithms, graphs, charts, numerical raw experimental results, instrumental outputs, other deliverables under sponsored agreements; intangible data such as statistics, findings, conclusions, other deliverables under sponsored agreement; and any other records of, or in any form that could be used for, reconstruction and evaluation of reported or otherwise published results of research.

#### **6. What are “essential” Research Records?**

“Essential” Research Records are those Research Records integral to substantiating grant applications or demonstrating compliance with contractual terms, if sponsored research; substantiating published research and patents, whether or not the research is sponsored; substantiating research described in grant proposals and other funding requests; and scholarship that should be considered for long-term preservation and access by the University Archives or the local archives of Schools. Essential research records also include any research data or materials designated as essential by the Schools, consistent with

the best practices for the relevant discipline.

**Under the Principles, Schools are required to specify for researchers the research Data and Materials considered essential, based upon the best practices of the relevant disciplines. The General Records Schedule (GRS) provides guidance for administrative, financial, and human resources records.**

**Principle 2: Research Records should be retained, generally, for a period of no fewer than seven (7) years after the end of a research project or activity. For this purpose, a research project or activity should be regarded as having ended after (a) final reporting to the research sponsor, (b) final financial close-out of a sponsored research award, (c) final publication of research results, or (d) cessation of academic or scientific activity on a specific research project, regardless of whether its results are published, whichever is later.**

**7. Must all tangible research materials be retained for a minimum of 7 years?**

Under certain circumstances, tangible research materials may be destroyed in advance of the seven year retention period. Investigators should maintain tangible research materials, such as research animals, biologic specimens, cell lines, and environmental samples, in accordance with the accepted practice of their own academic specialty or particular research community, or consistent with the terms of a sponsored research agreement, whichever is more rigorous in terms of retention period and/or requirements. If tangible research materials are destroyed in advance of the customary seven year retention period, however, researchers should document the date and circumstances of their destruction. **Under the Principles, Schools are required to establish policies for the retention and destruction of tangible materials, consistent with the best practices of the relevant discipline.**

**8. Are there any circumstances in which research records and data must be retained for longer than seven years?**

Researchers and others may be required by the University, School or department to retain Research Records beyond the seven-year period in certain circumstances, for example:

- In order to preserve or protect any intellectual property resulting from the research work, such as when the work is the subject of patent applications;
- As required by an external governmental or other funding source or sponsor; or if needed in connection with pending or reasonably anticipated litigation and other proceedings related to the sponsored research, such as fact-finding for research integrity, human subjects or animal use purposes. If, for example, a research integrity or human subjects research allegation is raised during the seven-year retention period, Research Records must be retained until the allegation is fully resolved, even if the process extends beyond the seven-year retention period;

- If a student is involved in the research activities, Research Data and Materials must be retained at least until the student's degree is awarded, or until it is clear that the student has permanently ceased his or her work; and
- If the research supports an FDA application, the researchers must comply with FDA document and data retention requirements to the extent that such requirements are more stringent, or of longer duration, than University requirements. See, e.g., 21 CFR 312.62 and 21 CFR 812.140

**9. Is a longer retention period required for research involving children or individuals with mental incapacity as subjects?**

A longer retention period is recommended if the research involves children or individuals with mental incapacity as subjects. PIs should consider retaining Research Data and Materials pertaining to such subjects at least until seven years after pediatric subjects have reached the age of majority or seven years after any mental incapacity has been removed. See, e.g., M.G.L. c. 260 s. 7. 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. Therefore, a longer retention period for Research Data and Materials relating to children and individuals with mental incapacity would allow the PI and the University access to all relevant records, for defense against any legal claims.

**10. What if the research involving children or individuals with mental incapacity is minimal risk?**

Some research with children or persons with mental incapacity may be very low risk, and in those cases, the cost of retaining all Research Data and Materials for such an extended period may outweigh any theoretical legal benefit. In considering whether and to what extent to retain Research Data and Materials in these studies, PIs should consider the nature and intensity of research interventions and the possibility of research-related harm to subjects, presumably deciding to honor an extended retention period in cases in which such interventions are more intense, complex and/or potentially harmful. In making this determination, PIs must consult with their own departmental administration and their cognizant IRB. PIs may also for this purpose consult with the Office of General Counsel and the Provost's office.

**11. Does the 7 year retention requirement apply to documents subject to IRB destruction or de-identification mandates?**

IRB destruction or de-identification mandates take precedence over the University's data retention requirements for Research Data and Materials. When considering proposed study protocols or amendments thereto, IRBs may direct investigators to destroy Research Data

and Materials that identify research participants in order to safeguard the anonymity of the participants. Such destruction of records may, for example, be indicated in some survey research, in which there may be no need to retain participant identities. In such cases, investigators should, in the first instance, adhere to any information or document destruction procedures contained in an IRB-approved protocol, and respect this policy and the GRS schedule in regard to all other Research Records.

**12. Does the 7 year retention requirement apply to confidential or third-party data subject to data use agreements that require return or destruction of data prior to the expiration of the retention period?**

The terms of any data use agreement<sup>1</sup> for confidential or third-party data take precedence over the University's data retention requirements.

**13. How should Research Records be handled after the specified period of retention expires?**

Before destroying Research Records, researchers should check the GRS for retention guidelines for administrative, financial and human resources records and consider, among other things, whether Research Records need to be retained for additional scientific or scholarly activities, whether Research Records may be needed for establishing or defending intellectual property rights, whether the Research Records may have significant future scientific or academic value, and/or whether the Research Records may have value as historical sources, including for the history of science or the history of other academic disciplines.

In deciding whether and how to retain Research Records during and after the expiration of the required retention period, or before destroying Research Records, researchers should consult with the University Archives or their own School's archives at HMS or HBS, which can answer questions on basic retention requirements and seeks, often in coordination with other units of the University, to preserve, or assist in the preservation of, University records that have special significance or historical or academic value. See <http://hul.harvard.edu/fmo/> and <http://grs.harvard.edu>. Researchers concerned about intellectual property value of Research Records whose required retention period has passed may consult with the University's Office of Technology Development.

In destroying or otherwise disposing of Research Records after the required retention period has expired, researchers should seek to assure both safety and completeness of destruction, and should consider, among other concerns, biosafety, radiologic safety, and

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<sup>1</sup> Please note that all DUAs must be reviewed by a School's IRB, School Security Officer and relevant Sponsored Programs Administrator (or School officials to whom this responsibility has been delegated by the cognizant Sponsored Programs Administrator) before the DUA may be accepted and signed by the Office of Sponsored Programs, the HMS Sponsored Programs Administrator or the HSPH Sponsored Programs Administrator. No researcher may accept a DUA without such review or sign a DUA.

the privacy and confidentiality of human resources and human subjects information. Schools should provide further discipline-specific guidance as to which types of Research Data and Materials researchers should consider destroying after 7 years.

**14. Does the 7 year retention period apply to information compiled to create a teaching case?**

Schools whose faculty members prepare teaching cases should establish local policies regarding record retention requirements that are consistent with the best practices of the relevant discipline.

**Principle 3: As needed, researchers and staff must make Research Records available to the University so that it may respond to federal audits or other official requests, respond to subpoenas or other document demands, and conduct other internal and external oversight activities.**

**15. May researchers retain custody and control of their own Research Records or must such records be retained in a central University repository?**

The University does not require researchers to maintain research on a central University repository, but does require that researchers make Research Records available to School and University officials when necessary to conduct or respond to audits and investigations, and/or to defend the use of research funds or the integrity of the research.

**16. How must Research Records be stored?**

Research Records normally should be maintained in the office, laboratory or department where they are created and used, or otherwise on University premises or in electronic computing systems maintained by the University<sup>2</sup>. Principal Investigators and other University faculty and staff who lead or administer research projects are responsible for maintaining an orderly system for recording, retaining, accessing, and storing their Research Records, and for communicating such systems and their proper use and access to the members of their research teams and other appropriate administrative and academic personnel, including administrative leadership of their department(s). Research Data and Materials in particular must be stored in compliance with the Harvard Research Data

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<sup>2</sup> As of the date of initial adoption of these FAQs (July 31, 2012), University electronic systems may not be fully capable of handling all electronic storage related to research, due to technological limitations. As stated in this policy, researchers should use Harvard electronic systems to store and transmit Research Records whenever possible, and must migrate Research Records to Harvard systems when capacity becomes available. When it is not possible to use Harvard systems due to a lack of internal capacity, researchers should only use external data storage providers that have been approved by the University CIO. This is especially important in the case of research involving high-risk confidential information, because external data storage providers may lack adequate security measures. In any situation involving storage of Research Records on systems external to Harvard, it remains the researcher's obligation to assure that such Research Records can promptly be made available to the University, school and department, as needed, for administrative, audit and research integrity purposes.

Security Policy (<http://www.security.harvard.edu/research-data-security-policy>) and, in the case of Research Data and Materials relating to human subjects research, in a manner that complies with all applicable IRB and University requirements, and with any relevant contracts, data use agreements and federal regulations.

**17. Must all Research Records be stored on-campus to ensure University access?**

In some cases, as in research that is collaborative with other institutions, electronic or other Research Records may be compiled, stored or maintained outside of Harvard systems as a requirement of receiving research funding. It is important in these circumstances, as in other circumstances in which there is a compelling need to store Research Records outside of Harvard systems, that subcontracts, subawards and vendor agreements entered into for such research contain provisions that incorporate a reference to the Principles and FAQs and require adherence to the same, thus assuring that Harvard can access Research Records, as needed for institutional, School or departmental purposes. When interacting with Harvard sponsored research offices (OSP, HMS SPA, HSPH SPA and OTD) about implementation of their sponsored research awards or expenditure of sponsored research funds, it is the responsibility of researchers and research administrators to call attention to any practices by which Research Records will be compiled, stored or maintained by third-parties or otherwise outside of Harvard or the University's electronic systems. Sponsored research officials will thereby be able to assist with subcontracts, subawards and/or vendor agreements that acknowledge these practices and allow for Harvard access, as needed, to the Research Records.

**18. How can access be assured if Research Records are produced, maintained, or stored off-campus?**

When researchers, research team members or administrators produce or obtain Research Records in non-University locations, or when Research Records are produced or obtained by subcontractors, subawardees or vendors whose activities in this regard are funded by or under University sponsored research, it is the responsibility of Principal Investigators, all research team members and administrators to ensure that: (a) these Research Records are stored and maintained safely and appropriately; (b) the Research Records are provided to the University at the earliest opportunity and in compliance with any legal constraints on their transfer, or are otherwise secured outside of the University, but with assured access for the University; and (c) the subcontractors, subawardees and/or vendors will provide immediate access to the Research Records when sought by the University, or by the University's agents or designees, either for the University itself or for funders/sponsors.



**Principle 4: The record keeping systems or practices used by Harvard researchers and staff should allow ready and full access by the University to the Research Records over their entire retention period. Such systems include, but are not necessarily limited to, electronic systems owned by the University or those located on the physical premises of the University. To the extent that use of University computing or other electronic systems for these purposes is not reasonably possible or is not preferred (e.g., research conducted off-site, electronic records that are required to be stored on non-Harvard servers, research conducted in collaboration with researchers whose primary affiliation is not Harvard), Harvard researchers and staff should assure that such Research Records are readily available to the University, if needed by the University for oversight purposes.**

**19. How do researchers ensure that Research Records are accessible?**

In general, Research Records are accessible because they are housed in Harvard facilities and/or on Harvard equipment. By working with their cognizant submitting office (OSP, HMS SPA, HSPH SPA), researchers and their administrators can insert provisions in subcontracts, subawards, data use agreements, and material transfer agreements (among other documents), that will assure Harvard access to Research Records housed off-campus. However, researchers should note that preservation of Research Records alone may not be sufficient to allow access, due to changes in technology. The need for continued access to essential Research Records during the entire retention period should therefore be considered by researchers in planning for compliance with this policy. University Archives or local records management programs are available to provide guidance to researchers in planning for compliance with these requirements.

**20. Under what circumstances will the University seek to access Research Records?**

The University, School and departmental administration may access Research Records for a variety of purposes, including the need to respond to audit requests or other requests for access to research information from funders or prime award recipients, to comply with valid subpoena requests or other court- or agency-ordered discovery, to defend claims asserted against the University, or when necessary, to investigate allegations of research misconduct or other regulatory violations. *See, e.g.*, Public Health Service Policies on Research Misconduct regulations, 42 CFR Parts 50 and 93 and National Science Foundation's Research Misconduct regulations, 45 CFR 689. In certain circumstances, such as the investigation of research misconduct and other regulatory violations, and consistent with School policies, the University may be required to, or may otherwise have a need to, take immediate custody and control of Research Records, including Research Data and Materials. *See, e.g.*, FAS research misconduct policy at: <http://www.fas.harvard.edu/~research/greybook/misconduct.html>, HMS research

misconduct policy at: <http://hms.harvard.edu/public/coi/policy/misconduct.html>, and PHS and NSF policies referenced above.

**21. Who, in addition to the Principal Investigator, should have access to research data, codes, etc. in case the PI becomes unavailable for some reason?**

As a matter of good administrative practice, Principal Investigators should take steps to assure that there are means for others to access research data if the PI becomes unavailable. This might mean sharing access codes, instructions or other means of access with collaborators, assistants or a departmental administrator.

**22. May Research Records be transferred to a new institution upon the departure of a Principal Investigator?**

The Principles and this guidance are not intended to alter Harvard's longstanding institutional practice of assisting, within reasonable parameters, faculty who wish to move from Harvard and to continue ongoing scholarship and research at another academic institution. However, other institutional values also must be respected, even as Schools and the University seek to facilitate the transition of a departing faculty member's ongoing research and scholarship. For example, when Principal Investigators who have been or are involved in sponsored research leave Harvard, Schools should have a process that allows the departing PI to take with him or her aliquots of specimens and/or copies of Research Data and Materials that the PI has gathered or produced, as long as: (1) when appropriate, originals of the relevant Research Data and Materials remain at Harvard, (2) the removal of aliquots or copies of Research Data and Materials does not conflict with Harvard's Intellectual Property Policy, (3) the removal of aliquots or copies does not harm the integrity of an ongoing collaborative research project, or (4) the removal of aliquots or copies does not contravene agreements between Harvard and third parties. In most cases, conflicts can be avoided simply through the renegotiation of agreements transferring institutional responsibilities to the new institution.<sup>3</sup> It is the responsibility of the Schools to develop an exit process through which a School can sort through what research records and materials, if any, must be retained on-campus as originals or copies, taking into account the needs and rights of those researchers who remain at the University, the need to maintain the integrity of any ongoing research, and the need to comply with sponsored research terms and conditions, as well as the needs of the departing Principal Investigator to continue his or her research. This process should be developed by each School, in consultation with faculty members and the Office for Technology Development.

Research Records that are not Research Data and Materials, such as financial, administrative and human resource records, may not be removed from Harvard, either in original form or as copies.

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<sup>3</sup> For example, if a PI wishes to take a biological material that had been obtained from a third party under a material transfer agreement (MTA), the Office of Technology Development can assist in terminating the existing MTA and informing the new institution of its need to enter into a new MTA with the provider of the material.

**23. May students and post-doctoral fellows take research data and materials with them when they leave the University?**

Ordinarily, when researchers, including students and postdoctoral fellows, who have been or are involved in sponsored research projects leave Harvard, they may take copies of Research Data and Materials from projects on which they have directly worked, unless the process of copying or division could damage or render unusable the Research Data and Materials or could harm the integrity of an ongoing research project,<sup>4</sup> or unless transfer of copies of the Research Data and Materials is restricted by the University IP policy or by an agreement between Harvard and a third party.

**Principle 5: The record keeping systems or practices used by Harvard researchers and staff should be designed to include the retention of important written correspondence (including mail and electronic mail, and copies of reports, analyses and progress reports) related to their research. The scope of the correspondence that should be retained should be sufficient to enable an independent party reviewing that correspondence to identify and understand primary findings, major events, and major strategic decisions or judgments made in the course of that research.**

**24. How must emails be stored/retained? Must all emails related to research be retained/made accessible?**

To the greatest extent reasonably possible, electronic mail relating to University sponsored research should be routed through the University's email network or otherwise archived on University-owned equipment. Harvard researchers should use their best efforts to use only their Harvard.edu email accounts to send and receive messages relating to their research work or any potentially patentable inventions that may arise from such work. When this is not possible, as in cases in which the University electronic mail system is not reasonably available, is inoperative, or is unable to send and receive essential data, other secure electronic mail systems may need to be used on a temporary basis, but in such cases, researchers should, as soon as practicable, transfer all such records to the University's electronic systems. In any period before such transfer to Harvard systems has been completed, researchers must make all such electronic Research Records immediately available to the University upon request.

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<sup>4</sup> Schools should be cognizant of and examine on a case-by-case basis the special issues associated with certain research projects conducted in a team setting. For a student or postdoctoral fellow who has worked on or assisted in research projects in such a setting, the Principal Investigators or laboratory directors on whose projects the student or postdoctoral fellow has worked must assess whether allowing that person to remove copies of their own Research Data and Materials would be appropriate, given that those Research Data and Materials might constitute an incomplete record of the entire research. In these situations, Principal Investigators and laboratory directors should use their best judgment as to what copies of Research Records, if any, may be removed. In making these determinations, Principal Investigators and laboratory directors should seek to assist the departing student or postdoctoral fellow, but only insofar as this does not compromise the integrity of the overall research project, their own ability to comply with sponsored research terms or conditions, or the various requirements of this policy and other University regulations.

## 25. What types of grant-related correspondence must be retained?

In conjunction with sponsored research, the following written correspondence must be retained in GMAS: (1) Grant application; (2) Renewal application; (3) Quarterly reports/progress reports; (4) Any emails that address budget issues; (5) Any emails that address the scope of the work; and (6) Grant agreements and any amendments.

**Principle 6: Harvard faculty and staff should be mindful that for research that has led to major academic findings or major scientific discoveries, a wider and more inclusive set of Research Records should likely be maintained, for historical purposes and for the protection of intellectual property.**

## 26. How does this Principle operate in practice?

Recognizing what may be a major academic finding or major scientific discovery is not always possible at early stages of a project. Faculty are not expected to foretell the future. However, this principle should be kept in mind and when it does happen that a finding or discovery is recognized as a breakthrough or of potential historical significance, the usual record retention practices that apply to such information should be reconsidered in order to determine if a larger than usual set of records should be archived for posterity. For further information, please reference the guidance and appendices developed by the University Archivist and the head of Preservation, Conservation and Digital Imaging entitled **Guidance for the Long Term and Permanent Preservation: Principle 6.**

## 27. How do faculty ensure that what they determined was essential at the outset is not found to be too limited when there actually is a major academic finding or scientific discovery?

There is no practical way to assure that all information one might wish to keep concerning major academic findings or scientific discoveries will have been kept at the time one recognizes the significance of such findings or discoveries. The important thing to keep in mind is that such events occur and that, as an academic institution, Harvard places value on maintaining the records of these singularity events for the benefit of future teaching and scholarship. For further information, please reference the guidance and appendices developed by the University Archivist and the head of Preservation, Conservation and Digital Imaging entitled **Guidance for the Long Term and Permanent Preservation: Principle 6.**