University of Massachusetts Chan Medical School

Guide to Research Data Retention and Access

Maintaining accurate and appropriate **research data**, and access to those data (including data sharing), is essential to research. It is necessary to document and substantiate findings, to make data supporting those findings findable, accessible, interoperable, and reusable (FAIR), to protect intellectual property rights and the integrity of our research, to facilitate management of the research program of the University of Massachusetts Chan Medical School (UMass Chan), to enable scholarly communications and the advancement of science, and to comply with federal regulations, contractual requirements, UMass Chan policies, and sponsor requirements. This guide is for all UMass Chan faculty, academic staff, visiting scholars, postdoctoral fellows and other trainees, research staff, students, and any other persons at UMass Chan involved in the design, conduct, or reporting of research at or under the auspices of UMass Chan, and it applies to all research projects on which those individuals work, regardless of the source of funding for the project.

Definitions

Data access is defined as the principles and practices by which data are made available and accessed, to whom, and by what methods, during and following a research activity. Data access involves the authorization and control of who can access data and what they can do with it, such as sharing, storage, management, and destruction.

Data owner is the person or entity responsible for the accuracy and integrity of the data and has rights to the use of the data. There may be more than one entity that has rights to a data set or element, and rights may be defined in a data use agreement (DUA). For data generated at UMass Chan, both the research team and the institution may have rights to the data, depending on the nature of the sponsorship agreement.

Data retention is defined as the act of managing, storing, and preserving research data during and after a research activity to meet the scientific, institutional, sponsor, legal, and contractual obligations of the research activity.

Data security administrator is a person appointed by the research data custodian to protect the data by ensuring that the data are stored in an appropriately secure location, that access to those data is managed (for example by approving access), and that there are appropriate provisions for ensuring data integrity (such as backup copies).

Research data are defined as any recorded information generated during the process of research commonly accepted in the scientific community as necessary to understand and validate research findings. This includes all information useful for the reconstruction and evaluation of reported results of research and the events and processes leading to those results, regardless of the form or the media on which they are recorded. Research data may be, but are not limited to, writings, email, research notes, physical or electronic laboratory notebooks, case history records, study protocols, computer files or other electronic data, film, photographs, sound or video recordings, pictorial reproductions, drawings, designs or other

graphical representations, software programs including scripts, prompts and other recorded computational instructions, data files and databases, workflow charts, statistical records, and other research data generated as a result of a research process. Research data excludes tangible research property produced in research such as biospecimens, biological materials and prototype devices, and instrumentation with which research is carried out but may include associated meta data.

Research data custodian is a person contractually obligated to accomplish a research activity and have the responsibility of ensuring the appropriate collection, management and storage of, access to, retention, and sharing of research data. A research data custodian is typically the principal investigator (PI) of a research activity.

Research Data Ownership

Research data may be acquired or generated while individuals are pursuing research studies as faculty, staff, or students of UMass Chan, or by visiting scientists utilizing the facilities of UMass Chan. At UMass Chan, the PI is typically considered the **research data custodian** and is responsible for ensuring appropriate and compliant acquisition, generation, management, and storage of research data, for managing access to those data, and for ensuring understanding and compliance with any policies or agreements. UMass Chan has an ownership stake in all research data covered under this guide unless UMass Chan explicitly waives ownership rights under an applicable research agreement, in which event the provisions of the research agreement shall control ownership.

If you have any questions about ownership, data sharing, or data transfer, you can obtain guidance as follows: Office of Clinical Research (for industry sponsored grants), Office of Sponsored Programs (for government funded grants and foundation funded grants), or Office of Innovation and Business Development (BRIDGE; for commercial projects involving intellectual property). If a research data custodian leaves the institution, they must leave the original **research data** at UMass Chan but can work with the appropriate office above to take a copy of those data with them. Transfer of data outside of UMass Chan requires a formal, signed agreement. Exclusive rights to reuse or publish data will not be assigned to commercial publishers or other agents unless this is a condition of funding or a result of UMass Chan policy or licensing choices.

Research Data Access

As stated above, the **research data custodian** is responsible for managing access to those data, and for ensuring understanding and compliance with any policies or agreements. Access is determined by the needs of the research project and in compliance with UMass Chan policy, federal and state regulations, and sponsor and/or **data owner** requirements and agreements. These agreements and requirements are typically manifested through grant or contract agreements or through data use agreements (DUAs). The Office of Clinical Research (for industry sponsored clinical trials), Office of Sponsored Programs (for government funded grants and foundation funded grants), or Office of Innovation and Business Development (BRIDGE) (for commercial projects involving intellectual property) can provide guidance on contractual,

sponsorship, and compliance questions. For guidance on access control and access management, please contact the Chief Research Computing Officer (CRCO) for basic science data and the Chief Research Informatics Officer (CRIO) for any data set that involves human subjects data. Considerations affecting access include:

- The research data custodian determines and manages research data access during the course of an active research activity. Access typically includes members of the research project team and may include external researchers.
- The research data custodian and UMass Chan (CRCO or CRIO) jointly determine and work with IT to manage storage and access following a research activity. Such access must meet institutional policy, sponsor, and contractual requirements.
- The research data custodian is often required by funding agencies of sponsored research to develop a data management and sharing plan. For example, NIH sponsored research activities must comply with the NIH Data Management and Sharing (DMS) Policy, which requires a DMS plan. Data access for grants that fall under the purview of this policy must follow the stated sharing methods in their DMS plan as per the NIH DMS Policy in effect for that sponsored agreement. The Lamar Soutter Library provides guidance, training, and tools to help researchers address NIH DMS Policy requirements.

Research Data Retention

Research data must be retained by the institution for a period of three (3) years after completion of a research project, unless a longer retention period is required by law or specified through agreement with a sponsor or **data owner** (Table). The institution must approve the systems in which the data are retained, and IT can provide assistance in identifying and using approved systems. Individual departments or programs may determine a longer, but not a shorter, period of retention.

For NIH-funded research, recipients generally must retain financial and programmatic records, supporting documents, statistical records, and all other records that are required by the terms of a grant, or may reasonably be considered pertinent to a grant, for a period of 3 years from the date the annual Federal Financial Report (FFR) is submitted. For awards under SNAP (other than those to Federal institutions), the 3-year retention period will be calculated from the date the FFR for the entire competitive segment is submitted. Those recipients must retain the records pertinent to the entire competitive segment for 3 years from the date the FFR is submitted to NIH. Federal institutions must retain records for 3 years from the date of submission of the annual FFR to NIH.

The Office of Management (Privacy and Compliance Group) and the Lamar Soutter Library at UMass Chan can provide guidance on data sharing methodologies, and the Chief Research Computing Officer (CRCO; basic science data) or Chief Research Information Officer (CRIO; data sets with human subjects data) can provide guidance on technical solutions to enable research data retention and access.

A research project can be regarded as having been completed after the latest of:

- final reporting to the research sponsor;
- final financial close-out of a sponsored research award or contract (e.g., NIH FFR);
- final publication of research results; or
- cessation of an academic or research project, regardless of whether its results are published.

Circumstances that may affect data retention and access:

- Data that must be kept for as long as necessary to protect intellectual property and complete patenting and licensing procedures for inventions resulting from UMass Chan research. Please confer with BRIDGE for guidance.

- Research data subject to additional regulatory bodies including, but not limited to, Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), or U.S. Food and Drug Administration (FDA), must comply with any applicable timelines for retention or default to university policy, whichever is longer. Please confer with the applicable regulatory body for guidance.

- Research data subject to Institutional Review Board (IRB) oversight must generally comply with any applicable timelines for retention or default to university policy, whichever is longer. However, an IRB may direct investigators to destroy research data at an earlier timepoint to minimize risks to subjects, including the risk of breach of confidentiality (e.g., audio recordings for which transcription and quality checks are complete, identifiers recorded during screening for individuals who ultimately do not enroll in the research). Please confer with the IRB for guidance.

- If any charges regarding the research arise, such as allegations of scientific misconduct or improper charging of costs, data must be retained at least until such charges are fully resolved or for such other period as may be required by university policies or regulations.

- If a student or trainee (e.g., PostDoc) is involved in the research, data must be retained for at least three years after the student's degree is awarded or the advisor determines that the student or trainee has abandoned work on the project.

Table: Summary of Research Retention Requirements

Type of Record	Baseline Retention	Additional considerations
Regulatory Documentation, Including: • IRB Approval letters • IRB Correspondence	Minimum of three years after completion of the research or closure with the IRB[1]	Longer retention for: • HIPAA (Waiver of Authorization, accounting of disclosures): minimum of 6 years[2] • FDA: minimum of 2 years past approval or discontinuation, or minimum of 2 years past final report for electronic records[3]

[1] See HRP-103, Investigator Manual, p. 17
[2] See HRP-103, Investigator Manual, p. 17
[3] See HRP-103, Investigator Manual, Appendix A-2, 21 CFR Part 11

• IRB approved versions of study documents • Correspondence with Federal Agencies		• ICH/GCP[4]: minimum of 2 years after last approval of marketing application or discontinuation. • Funder Agreement/Award: per terms of the Agreement/Award • Children: until age 21 • Legal hold (e.g. Open Records, Investigation/Compliance issue): as instructed by University[5]
Signed Informed Consent Forms (ICF) (if applicable)	Minimum of three years after completion of the research or closure with the IRB	Longer retention for: • HIPAA (combined ICF/Authorization): minimum of 6 years • FDA: minimum of 2 years past approval or discontinuation • ICH/GCP: minimum of 2 years after last approval of marketing application or discontinuation. • Funder Agreement/Award: per terms of the Agreement/Award • Children: until age 21 • Legal hold (e.g. Open Records, Investigation/Compliance issue): as instructed by University
Signed Authorization forms or IRB Waiver of Authorization (if applicable)	Minimum of 6 years	Longer retention for: • FDA: minimum of 2 years past approval or discontinuation (if combined with Authorization), or minimum of 2 years past final report for electronic records[6]ICH/GCP: minimum of 2 years after last approval of marketing application or discontinuation (if combined with ICF) • Funder Agreement/Award: per terms of the Agreement/Award • Children: until age 21 • Legal hold (e.g. Open Records, Investigation/Compliance issue): as instructed by University

[4] See HRP-103, Investigator Manual, Appendix A-3
[5] See Records Management, Retention, and Disposition Policy, Policy 1.02.04
[6] See HRP-103, Investigator Manual, Appendix A-2, 21 CFR Part 11

Accounting of Disclosures (if applicable)	Minimum of 6 years	

General research data	Minimum of three years after completion of the research or closure with the IRB	Longer retention for:
		• FDA: minimum of 2 years past approval or discontinuation, or minimum of 2 years past final report for electronic records[6]
		• ICH/GCP[7]: minimum of 2 years after last approval of marketing application or discontinuation.
		• Funder Agreement/Award: per terms of the Agreement/Award
		  ○ For Federal: minimum of three years, up to seven years, depending on specific funding agency requirement.[8]
		  ○ For National Institutes of Health Awards: per terms of award, NIH Grants Policy Statement (3 years following submission of the FFR[9]) and data management and sharing plan (DMSP)[10]
		• Children: until age 21
		• Legal hold (e.g. Open Records, Investigation/Compliance issue): as instructed by University

FDA regulated Human Research, including: • Informed Consent documentation • Deviations • Adverse Events • Drug/Device handling records. • Case Report Forms • Source Documents	Minimum of 2 years past approval or discontinuation, or minimum of 2 years past final report for electronic records[11]	Longer retention for: • Source Documents: portions may be subject to record retention policy of holding organization i.e. UMass Memorial Medical Center. • HIPAA (combined ICF/Authorization): minimum of 6 years • ICH/GCP: minimum of 2 years after last approval of marketing application or discontinuation.

[7] See HRP-103, Investigator Manual, Appendix A-3
[8] OMB Circular A-110, (Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations); various regulations including 45 CFR 74 and 45 CFR 92
[9] See Section 8.4.2 of the NIH Grants Policy Statement
[10] See NIH Data Management and Sharing Policy
[11] See HRP-103, Investigator Manual, Appendix A-2, 21 CFR Part 11

		• Funder Agreement/Award: per terms of the Agreement/Award
		  ○ For Federal: minimum of three years, up to seven years, depending on specific funding agency requirement.[12]
		  ○ For National Institutes of Health Awards: per terms of award, NIH Grants Policy Statement (3 years following closeout of grant/contract agreement[13]) and data management and sharing plan (DMSP)[14]
		• Children: until age 21
		• Legal hold (e.g. Open Records, Investigation/Compliance issue): as instructed by University

Student-led Research	Minimum of three years after award of degree or abandonment.	Longer retention as outlined above.

Research Data Retention and Access Responsibilities

University Responsibilities

UMass Chan responsibilities regarding access and retention of Research Data are:

- Depending on the agreement, OSP or OCR will provide appropriate grant and contract agreements that may involve data rights;
- The Department Chair is responsible for ensuring that documentation and data are retained institutionally when faculty or other UMass Chan researcher leaves the institution;
- The Office of Student Affairs and HR will enable students, postdoctoral fellows, staff, and other collaborators to access data from research in which they participate;
- The OoM will maintain an institutional policy framework, and business processes, to support effective research data retention and access;
- BRIDGE will manage the University's intellectual property rights; and
- The OoM will sequester or otherwise obtain access to research data for a required investigation pursuant to university policy and/or regulatory or sponsor requirements.

[12] OMB Circular A-110, (Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations); various regulations including 45 CFR 74 and 45 CFR 92

[13] See Section 8.4.2 of the NIH Grants Policy Statement

[14] See NIH Data Management and Sharing Policy

Principal Investigator (PI) Responsibilities

The PI responsibilities regarding the access and retention of research data are to:

- Act as **Research Data Custodian** in identifying, acquiring or generating, managing and retaining, and providing access to Research Data as custodian for UMass Chan.
- Cover the direct costs of storing research records, either physically or electronically, in partnership with the institution.
- Inventory and classify research data in partnership with IT as per the UMass Chan Data Classification policy, and determine in which systems or services these data are to be placed to ensure compliance with grant or contract requirements.
- Assign a **data security administrator** to ensure research data are appropriately protected.
- Review research data classifications annually.
- Ensure the protection, confidentiality, integrity, and availability of research data under their charge as per institutional and sponsor requirements and federal regulations.
- Verify research data access and retention, and comply with sponsor or other contractual agreements, and with institutional compliance and data security requirements.
- Provide data access, particularly for external parties, that meets institutional, legal, and IT security requirements.
- Confirm there are sufficient records to document the experimental methods and accuracy of the collection as well as the methods and accuracy of data interpretation.
- Verify research data are appropriately **findable**, **accessible, interoperable**, and **reusable** given the nature of the research and research data and agreements.
- Communicate the chosen system of data organization to all members of their research team, including appropriate administrative personnel.
- Comply with sponsor and **data owner** requirements for data access, sharing, and retention.
- Comply with UMass Chan's rules on the ownership of data associated with inventions or tangible research property that the University wishes to commercialize.
- Manage data disposition as per institutional, grant or contract, or **data owner** requirements and as per UMass Chan policy once data have exceeded their retention period.

Responsibilities of the Department of Information Technology

- Provide and manage storage offerings that ensure security, confidentiality, accessibility, and integrity of research data compliant with UMass Chan institutional security standards.
- Recommend Data Classification of research data to the research data custodian as per the UMass Chan Data Classification policy.
- Provide information technology infrastructures (e.g., networks and transmission capabilities, data center facilities) and protections (e.g., monitoring, software patching, access control systems), that enable the processes of data retention and access for the UMass Chan research community and comply with relevant laws, regulations, and **data owner** requirements.

Policy Alignment

This guidance complies with the following policies:

- The UMass Chan Medical School Records Management, Retention, and Disposition Policy
- The UMass Chan Medical School Data Classification Policy
- The University of Massachusetts Record Management, Retention and Disposition Policy

Contacts for Questions:

Research Computing Office
https://umassmed.sharepoint.com/sites/ChiefResearchComputingOfficer
Email: researchcomputingoffice@umassmed.edu

Office of Clinical Research: https://www.umassmed.edu/ccts/research-resources/ocr/
Email: ClinicalResearch@umassmed.edu

Office of Sponsored Programs
Tel: 508-856-2119
https://www.umassmed.edu/research/sponsored-programs/
Email: research.funding@umassmed.edu

BRIDGE
https://bridge.umassmed.edu/s/
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Information Technology and Information Security
Email: umasschanhelpdesk@umassmed.edu
Helpdesk Phone: 508-856-8643
Helpdesk Ticket: umassmed.service-now.com/

Office of Management (Privacy; COI; Research Data Security)
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