

Responsible Officer:	Vice President of Research and Innovation
Responsible Office:	Office of Research and Innovation
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Scope:	This policy applies to all Research Data and Tangible Research Materials generated by those at the University involved in the design, conduct, or reporting of research.

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I. POLICY SUMMARY

The Regents of the University of California owns all Research Data and Tangible Research Materials. To fulfill this obligation and in line with the University's mission of outstanding research, campus leadership and its Workforce Members are called to work in partnership, particularly as it relates to the management, retention, preservation, access and sharing of Research Data and Tangible Research Materials. Research Data and Tangible Research Materials must be retained as long as required by funders, publishers, campus policy, compliance or regulatory bodies, applicable law, relevant agreements, and in accordance with the standards of the Principal Investigators' scholarly disciplines. When Principal Investigators leave the University, Research Data and Tangible Research Materials remain the property of the Regents of the University of California, however, Principal Investigators may generally take copies of Research Data generated under their research projects.

II. DEFINITIONS

"Institutional Information": A term that broadly describes all data and information created, received and/or collected by UC.1

"Principal Investigator": The Workforce Member who has primary responsibility for a research project, including the design, conduct or reporting of the project, regardless of the source of funding or status of that project.²

"Research Data": Recorded Institutional Information reflecting original observations, regardless of the form or medium on which the information is recorded, that are generated or collected in connection with research: (1) within the course and scope of a Workforce Member's assigned or assumed duties; (2) using University research facilities or other University research resources; or (3) with funding from or through the University. Examples of recorded information include laboratory notebooks, field notes, digital images, data files, computer software, statistical records, etc. Administrative records, such as medical records, that are not created exclusively for research purposes are excluded from this definition and are governed by other UC policies. Please see FAQs # 2 and # 3 for more information.

"Tangible Research Materials": Tangible items produced or collected in the course of research: (1) within the course and scope of a Workforce Member's assigned or assumed duties; (2) using University research facilities or other University research resources; or (3) with funding from or through the University. Examples of tangible items

¹ See UC's Electronic Information Security Policy: https://security.ucop.edu/policies/ and https://security.ucop.edu/policies/quick-start-guides-by-role/researcher.html

² Contract and Grant Manual, <u>Chapter 1-520: Leadership of a Sponsored Project</u>.

³ Other research data maybe obtained through data or material transfer agreements, license agreements or other means. Such other research data that are not produced or collected by the University may be subject to third-party provider obligations, and should be handled in accordance with contractual commitments and applicable laws.

include biological specimens, archaeological and environmental samples, devices, prototypes, circuits, chemical compounds, genetically engineered organisms, cell lines, cell products, viruses, genetic material, plasmids, vectors, and chemical compounds.

"Workforce Members": An employee, faculty, staff, volunteer, contractor, researcher, student worker, student supporting/performing research, medical center staff/personnel, clinician, student intern, student volunteer or person working for UC in any capacity or through any other augmentation to UC staffing levels, who are involved in the design, conduct or reporting of research, regardless of the funding source for such activities.

III. POLICY TEXT

Ownership of Research Data and Tangible Research Materials

The Regents of the University of California owns all Research Data and Tangible Research Materials. University policies and guidance ensure that such ownership does not impede Workforce Members' ability to conduct research, transmit Research Data and Tangible Research Materials to collaborators, independently publish the outcomes of their research, or create scholarly works.

To fulfill the University's mission of outstanding research and the free exchange of ideas as well as to meet obligations with legal, funder, and collaborator requirements, campus leadership and its Workforce Members are called to work in partnership to ensure that all Research Data and Tangible Research Materials are properly curated, collected, securely stored, managed, and fully accessible. The Vice Chancellor for Research at each campus or their designee(s) are responsible for establishing procedures as it relates to the oversight, interpretation, and implementation of this Policy while Workforce Members must provide stewardship of Research Data and Tangible Research Materials throughout the research life cycle, from the point of research design to preservation.

Access to and Retention of Research Data and Tangible Research Materials

Access to and use and retention of Research Data and Tangible Research Materials is not only critical to substantiate results, but also to provide a foundation for the advancement of scholarship. Because new research may build upon data collected before the importance of such data could have been envisioned, it remains critical that Research Data and Tangible Research Materials are properly curated, collected, recorded, securely retained, managed, and appropriately accessible.

Principal Investigators must retain Research Data and Tangible Research Materials as long as required by funders, publishers, campus policy, compliance or regulatory bodies, applicable law, and as indicated in other relevant agreements. To ensure proper preservation, Principal Investigators must have systems or practices for maintaining and retaining Research Data and Tangible Research Materials in accordance with stated requirements and with the standards of their scholarly disciplines and campus departments. Principal Investigators are responsible for consulting these requirements

and must follow the most stringent requirement for retaining Research Data and Tangible Research Materials.

In addition to the above, Principal Investigators must take the following key circumstances into consideration when determining the retention period:

- **Inventions:** Research Data and Tangible Research Materials must be kept as long as necessary to protect intellectual property and complete patenting and licensing procedures for inventions resulting from University research.
- Allegations, Investigations and Litigation: If any allegations regarding the research arise, such as allegations of research misconduct, the Research Data and Tangible Research Materials must be retained by the University and maintained by the Workforce Member as long as required by any funder's requirements and/or federal regulations, but at least until all charges have been resolved and final action and appeals taken. If the Research Data or Tangible Research Materials are the subject of litigation or investigation, the University and Workforce Members will have a duty to preserve potentially relevant information until instructions have been provided regarding their disposition.
- FDA-Regulated Research: If a research project involves articles regulated by the U.S. Food and Drug Administration (FDA), consistent with 21 C.F.R. §§ 312.6 and 812.140, Principal Investigators must keep records for two years following the date a marketing application is approved for the product; or if a marketing application is not filed or FDA-approved, for two years after the investigation is terminated, completed, or otherwise discontinued and the FDA is notified.
- Student Participation in Research: If, in the course of advancement to degree, a student participates in the design, conduct or reporting of research, the Research Data and Tangible Research Materials connected to that research must be retained until the student has been awarded a degree or has abandoned the work.

IV. COMPLIANCE/RESPONSIBILITIES

The Vice Chancellor for Research at each campus or their designee(s) is responsible for each campus' oversight, interpretation, and implementation of this Policy. Further responsibilities are provided below.

A. Vice Chancellors for Research Responsibilities

The Vice Chancellor for Research at each campus or their designee(s) must:

- Establish local procedures as necessary for managing Research Data and Tangible Research Materials upon the separation or death of a Workforce Member, or when a Workforce Member can no longer fulfill their responsibilities.
- Assist in settling disputes between and among University researchers and research collaborators.

- Meet obligations concerning Research Data and Tangible Research Materials that may be required in research agreements or for complying with laws and regulatory requirements.
- Ensure that obligations undertaken to research sponsors and collaborators
 preserve University of California principles and policies, including retained rights
 for research and the right to publish.
- Sequester or otherwise obtain access to Research Data and Tangible Research Materials for an investigation, inquiry or investigation pursuant to University policies, legal processes, and/or regulatory or funder requirements.

B. Workforce Members Responsibilities

All Workforce Members are responsible for:

- Accurately curating, generating, collecting, recording, managing, and securely storing⁴ Research Data and Tangible Research Materials.
- Executing management practices for Research Data and Tangible Research
 Materials in accordance with the standards of their scholarly discipline and
 according to University policies, legal requirements, and the terms and conditions
 of applicable agreements entered into by the University with third parties,
 including but not limited to sponsored awards, material transfer agreements, or
 data use agreements.
- Consulting with their campus Vice Chancellor for Research or their designee(s) should there be any conflicts regarding obligations related to Research Data and Tangible Research Materials.

Workforce Members designated as Principal Investigators have additional responsibilities:

- Retaining Research Data and Tangible Research Materials on behalf of the University, as described in Section V below.
- Following best academic practices by ensuring that all necessary reviews and approvals are obtained with respect to collecting, managing, maintaining, and safeguarding Research Data and Tangible Research Materials prior to the collection, management, access, or disclosure of such data and materials.

V. PROCEDURES

Transfer of Research Data and Tangible Research Materials

Research Data and Tangible Research Materials shall remain the property of The Regents of the University of California. However, when Principal Investigators leave the

⁴ See UC's Electronic Information Security Policy: https://security.ucop.edu/policies/ and https://security.ucop.edu/policies/quick-start-guides-by-role/researcher.html

University, they may generally take copies of Research Data generated under their research projects as discussed below. Taking copies of Research Data may be restricted if such Research Data are: (i) subject to confidentiality or other legal restrictions (including but not limited to data and materials protected by privacy (e.g., the Health Insurance Portability and Accountability Act) or human subjects protections laws and regulations); (ii) germane to disputes and investigations; or (iii) necessary for patent protection. In these instances, the Principal Investigator must obtain permission from the Vice Chancellor for Research or their designee(s) to take copies of Research Data, in addition to other applicable approvals.

In addition to the requirements above, co-investigators may take copies of Research Data generated under their research projects (or the portions of projects) only with the permission of the Principal Investigator or, if the Principal Investigator and the co-investigator cannot reach agreement (or if the Principal Investigator is not reasonably available to give permission), with the permission of the Vice Chancellor for Research or their designee(s), in addition to other applicable approvals.

On a case-by-case basis, the campus in consultation with the Vice Chancellor for Research or their designee(s) may allow for the transfer of Research Data or Tangible Research Materials to another institution if it has been determined that the transfer of the Research Data and/or Tangible Research Materials would not impede other Workforce Members from continuing their research, does not conflict with legal or contractual requirements, and as long as the new institution accepts custodial responsibilities for the Research Data or Tangible Research Materials. The University may retain a copy of the Research Data or Tangible Research Materials and must retain access to the Research Data or Tangible Research Materials should that become necessary.

VI. RELATED INFORMATION

University Policies and Guidance

- University of California Regulation No. 4
- UC Copyright Ownership Policy
- UC Records Retention Schedule
- Electronic Communications Policy
- Electronic Information Security Policy
- California Digital Library Resources for Faculty
- Export Control Policy
- University Policy on Integrity in Research

• The Faculty Code of Conduct (APM 015)

Federal and State Rules and Regulations

- Federal Copyright Act
- California Labor Code § 2860

VII. FREQUENTLY ASKED QUESTIONS

Please refer to the attachment for Frequently Asked Questions.

VIII. REVISION HISTORY

Month XX, 2021 – This is a new policy. This policy expands on University of California Regulation No. 4 (APM-020).

IX. APPENDIX

N/A