

University of California Research Data

and Tangible Research Materials Policy

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

Ownership of Research Data by the UC Regents is a long-standing precept originally articulated in Regulation 4 (Academic Personnel Manual 020) where it states "Notebooks and other original records of the research are the property of the University." Regulation 4 was issued in 1958 and is still in effect. The intent of this Policy is to clarify the ownership of and responsibility for Research Data generated during the course of University Research, encourage active data management practices, and provide guidance with respect to procedures when a researcher leaves the University.

II. DEFINITIONS

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

"Principal Investigator": (s) (PI): The Workforce Member who has primary responsibilityUniversity-affiliated or employed Researcher(s) primarily responsible for a research project, including the design, conduct or and reporting of the project, regardless of the source of funding or status of that project. For the purpose of this Policy, the term PI is used whether or not it is a formal title designated by an external research sponsor.

"Research Data": Recorded Institutional Information information reflecting original observations and methods resulting from a scientific inquiry, regardless of the form or medium the media on which the information is they may be recorded, that are generated or collected in connection with research: (1) within the course and scope of a Workforce

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

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

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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. Research Data include material contained in laboratory notebooks, field notes, digital images, data files, computer software, statistical records, etc. Administrative records, such as medical records, (whether physical or electronic), but are separate from Scholarly & Aesthetic Works 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 # 3defined in the UC Copyright Ownership Policy. See FAQs #1-5 of this Policy for more information.

"Tangible University Research Materials": Tangible items produced or collected in the course of research: (1): Research conducted within the course and scope of a Workforce Member's Principal Investigator or University Researcher's assigned or assumed duties; (2), using University research facilities or other University research resources; or (3) with funding from funded by or through the University. Examples of tangible items 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 University Researchers: The University-affiliated or employed persons involved in the design, conduct or reporting of research, regardless of the funding source for such activities, including academic appointees, staff, postdoctoral scholars, research trainees, and medical center staff and clinicians. For the purpose of the Policy, students who participate in the design, conduct or reporting of a Principal Investigator's research project are subject to this Policy.

III. POLICY TEXT

³-Other research data may be 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.

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Exercising rights established by federal⁴ and state⁵ laws and University of California Regulation No. 4 (APM-020)⁶, the Regents of the University of California retain ownership of Research Data created by or at the direction of University Researchers or Principal Investigators during the course of University Research, unless specifically agreed otherwise by the University under sponsorship or other related agreements. Principal Investigators and University Researchers shall have a right to use Research Data for University purposes that they have generated or collected in the course of their University Research. This includes using Research Data for publishing the outcome of their research, creating scholarly works, and transmitting a copy of Research Data to others, unless precluded by law, policy or contract and subject to approval by the Principal Investigator.

As stewards of Research Data, Principal Investigators are responsible for ensuring that Research Data, whether generated by them or their research team, are recorded, stored, and used in accordance with the standards of their respective discipline, data management plan if applicable, campus department, and any requirements of applicable federal or state law or regulations, University policies and guidelines, and University contractual commitments.

The University, through the campus Vice Chancellors for Research or their designee(s), has an obligation to ensure that its resources are used appropriately and that there are effective systems in place for the maintenance, preservation, and accessibility of Research Data.

IV. COMPLIANCE / RESPONSIBILITIES

A. Ownership of Vice Chancellors for 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

⁴ Title 17, Section 201 of the Federal Copyright Act states: "(b) Works Made for Hire.—In the case of a work made for hire, the employer or other person for whom the work was prepared is considered the author for purposes of this title, and, unless the parties have expressly agreed otherwise in a written instrument signed by them, owns all of the rights comprised in the copyright."

⁵ California Labor Code §2860 provides that everything that an employee acquires by virtue of his/her employment (except compensation) belongs to the employer whether acquired during or after the term of employment.

⁶ Issued in 1958, University of California Regulation No. 4 (APM-020) states, "Notebooks and other original records of the research are the property of the University." This Policy elaborates on expectations established in Regulation No. 4.

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all Research Data and Tangible Research Materials are properly curated, collected, securely stored, managed, and fully accessible. The At each campus, the Vice Chancellor for Research at each campus or their designee(s) are is responsible for establishing procedures as it relates to the oversight, the interpretation, and implementation, and oversight of this Policy while Workforce Members must provide stewardship of and shall:

- Establish local policies or procedures as necessary for implementing this Policy, such as proposed minimum retention policies.
- Provide guidance to assure campus compliance with Research Data and Tangible obligations arising by law, regulation or agreement.
- <u>Have unfettered access to Research Materials Data for University purposes, including for the purposes of carrying out University responsibilities (including sequestration, as may be needed) related to conducting an inquiry or investigation pursuant to University obligations, such as research misconduct investigations, or in response to agency inquiries or legal process.</u>
- Implement local procedures to manage the transfer of Research Data or copies
 of Research Data, for example upon the separation or death of a University
 Researcher or when a University Researcher can no longer fulfill responsibilities.
 (See Section V.)
- Implement local policies and procedures to settle disputes over control, use, and publication of Research Data among University Researchers and their collaborators, according to established campus, academic discipline, and journal standards.

B. University Researchers

As stewards of the University's Research Data, University Researchers shall:

<u>Securely collect, record, manage, and store Research Data</u> 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 University Researchers are encouraged to leverage the California Digital Library, campus libraries, or other campus systemwide resources for advice on documenting 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

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have systems or practices for maintaining and retaining preserving Research Data.

- <u>Manage</u> and <u>Tangibleshare</u> Research <u>MaterialsData</u> in accordance <u>with stated</u> requirements and with the standards of their scholarly <u>disciplines</u> and <u>disciplines</u> and/or data management plan, and <u>University policies</u>, <u>legal requirements</u>, and <u>the terms and conditions of applicable third-party agreements (such as sponsored awards, material transfer agreements, or data use agreements).</u>
- Consult with the Principal Investigator and/or Vice Chancellor for Research (or their designee) for clarification of obligations and resolution of disputes related to Research Data.

C. Principal Investigators

<u>Principal Investigators shall, in the conduct of University Research, have the primary responsibility to:</u>

- Follow best academic practices with respect to collecting, recording, managing, and storing Research Data.
- Determine use of the Research Data by other University Researchers and collaborators on the project in accordance with relevant agreements and their scholarly discipline's practices, and taking into account the need for academic progress of academic appointees, post-doctoral scholars, degree candidates, and other students.

Retain Research Data on behalf of the University. Principal Investigators are responsible for knowing retention requirements of their scholarly discipline, campus departments. Principal Investigators are responsible for consulting these requirements and must follow, funding agencies, and applicable law and regulation, and for following the most stringent requirement for retaining Research Data and Tangible Research Materials.

- In addition to the above, of these multiple requirements. Principal Investigators
 must take the following key circumstances into consideration account when
 determining the retention period:
 - Inventions: Research Data and Tangible Research Materials must be kept as long as necessary to protect intellectual property and to complete University patenting and licensing procedures for inventions resulting from University research.
 - Allegations, Investigations and Litigation: If Research Data are the subject of 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 investigations or litigation or investigation, the University and Workforce Members will have a duty to University Researchers shall preserve potentially relevant information

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- until the Vice Chancellor for Research (or their designee), in consultation with Campus Counsel, issues 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. §§ 312.6312.6 and 812.140,812.140, Principal Investigators must keep records for two years or as long as required 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
 advancementadvancing to degree, a student participates in the design,
 conduct or reporting of research, the Research Data and Tangible
 Research Materials connected to that research mustshall be retained until
 the student has been awarded a degree, or until the student is no longer
 working on the project or has abandoned otherwise left the
 work. University.

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.

B. 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.

C. Workforce Members Responsibilities

All Workforce Members are responsible for:

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- Accurately curating, generating, collecting, recording, managing, and securely storing⁷ 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 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 Procedures in the Event that an Investigator Leaves the University

⁷-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

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When University Researchers (other than the Principal Investigator-or, if the) involved in a University Research project leave the University or the research project, they may take copies of Research Data that they generated or collected in the course of their University Research, subject to approval by the Principal Investigator and the co-investigator cannot reach agreement (or ifany applicable sponsor restrictions. Research Data, however, must be returned to and retained by 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 on behalf of the University, absent University approval of a transfer of the 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.

When a Principal Investigator leaves the University and a University Research project is to be moved to another institution, Research Data may be transferred or licensed to the new institution in accordance with a locally developed process that most likely involves approval from the applicable school, department and/or other academic units. The University may impose conditions on such transfer or may require the Principal Investigator to leave copies of the Research Data with the University. In addition, other University investigators associated with a collaborative research project may make copies of Research Data prior to a permitted transfer by the Principal Investigator, unless restricted by the specific terms of an applicable agreement with the sponsor of the research.

Any individual who leaves the University, whether to move to another institution or because of retirement or separation, must arrange with their school, department or center for the storage of any Research Data that remain at the University in accordance with any policy adopted by the applicable school, department or center. When the University permits a Principal Investigator to leave the University with Research Data, they must hold the Research Data in trust for the University. A departing Principal Investigator must return the Research Data to the University if requested. In addition, such Research Data must be available to external sponsors, designated governmental officials and other University investigators who are collaborators with the departing Principal Investigator.

VI. RELATED INFORMATION

University Policies and Guidance

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- University of California Regulation No. 4
- UC Copyright Ownership Policy
- <u>UC Records Retention Schedule</u>
- 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. <u>Implementing guidance related to this Policy may be posted on the UCOP Research Policy Analysis and Coordination (RPAC) website.</u>

VIII. REVISION HISTORY

Month XXFebruary 11, 20224 – This is a new policy. -This policy expands on University of California Regulation No. 4 (APM-020).

IX. APPENDIX

N/A