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OFFICE OF THE VICE PRESIDENT - RESEARCH AND INNOVATION

SANTA BARBARA • SANTA CRUZ

OFFICE OF THE PRESIDENT 1111 Franklin Street, 11th Floor Oakland, California 94607-5200

February 15, 2022

CHANCELLORS ACADEMIC COUNCIL CHAIR HORWITZ LABORATORY DIRECTOR WITHERELL ANR VICE PRESIDENT HUMISTON

Second Systemwide Review of Proposed Presidential Policy on University of California Re: **Research Data**

Dear Colleagues:

Enclosed for a second systemwide review is the draft Presidential Policy on University of California Research Data. This policy is new.

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 it is still in effect. The purpose of the new Presidential Policy on University of California Research Data is to 1) clarify ownership of and responsibility for research data generated during the course of University Research, 2) encourage active data management practices, and 3) provide guidance with respect to procedures when a researcher leaves the University.

The first systemwide review of the draft policy, entitled Presidential Policy on University of California Research Data and Tangible Research Materials, was launched on December 17, 2020. The Research Policy and Analysis (RPAC) unit within Research and Innovation received many thoughtful comments on the policy and made revisions based on that feedback, which is broadly summarized below.

Feedback on the Originally Disseminated Draft Policy

The feedback RPAC received regarding the proposed Presidential Policy on University of California Research Data and Tangible Research Materials generally falls into four categories:

- Concern that the scope of the University's ownership of research data and tangible research 1. materials is too broad, including by:
 - Extending into works that are copyrightable or works that are personal •
 - Imposing ownership on data and materials owned by third parties
 - Overreaching into tangible artifacts (e.g., archeological material excavated out of the ground) •
- 2. Concerns over how to implement the policy, including:
 - Costs •
 - Management plans •
 - Transfer process •

- 3. Concerns regarding unintended impact on core research facilities performing services on a feefor-service or recharge basis
- 4. Concerns over the unintended impact this policy might have on relationships with tribal nations

Revisions to the Originally Disseminated Draft Policy based on Feedback

RPAC made the following revisions and clarifications to the policy in response to the comments:

- 1. Explained that the intent of the policy is to clarify ownership of and responsibility for Research Data generated during the course of University Research and provide guidance with respect to procedures when a researcher leaves the University
- 2. Revised the definition of Research Data and rewrote the text of the policy concerning ownership to clearly differentiate between those data owned by Regents and those data covered under the Copyright Ownership Policy
- 3. Noted that there are exceptions to UC's ownership of Research Data when precluded by sponsorship or other related agreements
- 4. Removed the inclusion of tangible research materials in this policy
- 5. Revised the section of the policy related to procedures in the event that an investigator leaves the University

Systemwide Review

Systemwide review is a public review distributed to the Chancellors, the Chair of the Academic Council, the Director of the Lawrence Berkeley National Laboratory, and the Vice President of Agriculture and Natural Resources requesting that they inform the general University community, especially affected employees, about policy proposals. A second systemwide review also includes a 60-day full Senate review.

Employees should be afforded the opportunity to review and comment on the draft policy. Attached is a Model Communication which may be used to inform non-exclusively represented employees about these proposals. The Labor Relations Office at the Office of the President is responsible for informing the bargaining units representing union membership about policy proposals.

We would appreciate receiving your comments no later than **April 18, 2022**. Please submit your comments to <u>RPAC@ucop.edu</u> with the subject line "Research Data Policy Comments." If you have any questions, please contact Agnes Balla at <u>agnes.balla@ucop.edu</u> or (510) 987-9987.

Sincerely,

Theresa a Maldonado

Theresa A. Maldonado, Ph.D., P.E. Vice President, Research & Innovation University of California Office of the President

Enclosures:

- 1) Draft Presidential Policy University of California Research Data (clean copy)
- 2) Draft Presidential Policy University of California Research Data (redline copy)
- 3) Draft Presidential Policy University of California Research Data FAQs
- 4) Model Communication

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cc: President Drake Provost and Executive Vice President Brown Executive Vice Chancellors/Provosts Executive Vice President and Chief Operating Officer Nava Senior Vice President Bustamante Vice President and Vice Provost Gullatt Vice President Lloyd Vice Provost Carlson Vice Provosts/Vice Chancellors of Academic Affairs/Personnel Deputy General Counsel Woodall Associate Vice Provost Lee Assistant Vice Provosts/Vice Chancellors for Academic Personnel **Executive Director Baxter** Executive Director and Chief of Staff Henderson **Executive Director Silas** Chief of Staff Kao Chief of Staff Levintov Chief of Staff Peterson Chief Policy Advisor Marisa McAuliffe Director Grant **Director Roller Director Sykes** Associate Director Fishel Manager Crosson Analyst Durrin Policy Advisory Committee **Executive Director Motton** Associate Director DeMattos Research Policy Manager Balla



University of California Research Data Policy

Responsible Officer:	cer: Vice President of Research and Innovation	
Responsible Office:	Office of Research and Innovation	
Issuance Date:	[Issuance Date]	
Effective Date:	[Effective Date]	
Last Review Date:		
Scope:	This policy ("Policy") applies to all Research Data created during the course of University Research.	

Contact:	Name
Title:	Title
Email:	Name@ucop.edu
Phone:	Name@ucop.edu (510) 987-XXXX

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I. POLICY SUMMARY

Ownership of Research Data by the UC Regents is a long-standing precept originally articulated in Regulation 4 (<u>Academic Personnel Manual 020</u>) 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

Principal Investigator(s) (PI): The University-affiliated or employed Researcher(s) primarily responsible for a research project, including design, conduct and reporting, regardless of the source of funding. 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 information reflecting original observations and methods resulting from a scientific inquiry, regardless of the form or the media on which they may be recorded. Research Data include material contained in laboratory notebooks (whether physical or electronic), but are separate from Scholarly & Aesthetic Works that are defined in the UC Copyright Ownership Policy. See FAQs #1-5 of this Policy for more information.

University Research: Research conducted within the course and scope of a Principal Investigator or University Researcher's assigned or assumed duties, using University resources, or funded by or through the University.

University Researchers: The University-affiliated or employed persons involved in the design, conduct or reporting of research regardless of the funding source, 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

Exercising rights established by federal¹ and state² laws and University of California Regulation No. 4 (APM-020)³, 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. Vice Chancellors for Research

At each campus, the Vice Chancellor for Research or their designee(s) is responsible for the interpretation, implementation, and oversight of this Policy 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 obligations arising by law, regulation or agreement.

¹ 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."

² 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.

³ 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.

- Have unfettered access to Research 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.
- 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:

- Securely collect, record, manage, and store Research Data throughout the research life cycle, from design to preservation. University Researchers are encouraged to leverage the California Digital Library, campus libraries, or other campus systemwide resources for advice on documenting and preserving Research Data.
- Manage and share Research Data in accordance with the standards of their scholarly discipline, and/or data management plan, and University policies, legal requirements, and the terms and conditions of applicable third-party agreements (such as sponsored awards, material transfer agreements, or data use agreements).
- 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

Principal Investigators shall, in the conduct of University Research, have the primary responsibility to:

- 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, funding agencies, and applicable law and regulation, and for following the most stringent of these multiple requirements. Principal

Investigators must take the following key circumstances into account when determining the retention period:

- Inventions: Research Data must be kept as long as necessary to protect intellectual property and to complete University patenting and licensing procedures for inventions.
- Allegations, Investigations and Litigation: If Research Data are the subject of any allegations, investigations or litigation, the University and University Researchers shall preserve potentially relevant information until the Vice Chancellor for Research (or their designee), in consultation with Campus Counsel, issues instructions regarding 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 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 advancing to degree, a student participates in the design, conduct or reporting of research, the Research Data connected to that research shall be retained until the student has been awarded a degree, or until the student is no longer working on the project or has otherwise left the University.

V. PROCEDURES

Procedures in the Event that an Investigator Leaves the University

When University Researchers (other than the Principal Investigator) 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 any applicable sponsor restrictions. Research Data, however, must be returned to and retained by the Principal Investigator on behalf of the University, absent University approval of a transfer of the Research Data to another institution.

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.

University of California – Policy Research Data Policy

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

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

VIII. REVISION HISTORY

February 11, 2022 – This is a new policy. This policy expands on University of California Regulation No. 4 (APM-020).

IX. APPENDIX

N/A





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	
Issuance Date:	[Issuance Date]	
Effective Date:	[Effective Date]	
Last Review Date:		
Scope:	This policy <u>("Policy")</u> applies to all Research Data and Tangible Research Materials generated by those at <u>created during</u> the <u>course of</u> University involved in the design, conduct, or reporting of researchResearch.	

Contact:	Name
Title:	Title
Email:	Name@ucop.edu
Phone:	<u>Name@ucop.edu</u> (510) 987-XXXX

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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.⁴

"Principal Investigator": (s) (PI): The Workforce Member who has primary responsibility University-affiliated or employed Researcher(s) primarily responsible for a research project, including the design, conduct or<u>and</u> reporting of the project, regardless of the source of funding or status of that project.². 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 mediumthe 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: <u>https://security.ucop.edu/policies/</u> and 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.

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.³ Examples of recorded information include <u>.</u> 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.

"TangibleUniversity Research Materials": Tangible items produced or collected in the course of research: (1): Research conducted within the course and scope of a Workforce Member'sPrincipal Investigator or University Researcher's assigned or assumed duties; (2), using University research facilities or other University research resources; or (3) with funding fromfunded 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 <u>University Researchers:</u> 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.

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.

all Research Data and Tangible Research Materials are properly curated, collected, securely stored, managed, and fully accessible. The

<u>At each campus, the</u> 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 Tangibleobligations arising by law, regulation or agreement.
- 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.
- 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

have systems or practices for maintaining and retainingpreserving Research Data.

- <u>Manage</u> and <u>Tangibleshare</u> Research <u>MaterialsData</u> in accordance-with stated requirements and with the standards of their scholarly <u>disciplines and discipline</u>, and/or data management plan, and University policies, legal requirements, and the terms and conditions of applicable third-party agreements (such as sponsored awards, material transfer agreements, or data use agreements).
- 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

Principal Investigators shall, in the conduct of University Research, have the primary responsibility to:

- 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 considerationaccount 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 <u>Research Data are the</u> <u>subject of</u> 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 <u>, investigations or</u> litigation or investigation, the University and Workforce Members will have a duty toUniversity Researchers shall preserve potentially relevant information

until <u>the Vice Chancellor for Research (or their designee)</u>, in consultation <u>with Campus Counsel</u>, 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. §§ <u>312.6312.6</u> and <u>812.140,812.140</u>, 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:

- Accurately curating, generating, collecting, recording, managing, and securely storing² 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 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

² See UC's Electronic Information Security Policy: <u>https://security.ucop.edu/policies/</u> and https://security.ucop.edu/policies/quick start guides by role/researcher.html

<u>When University Researchers (other than the Principal Investigator or, if the) involved</u> 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 coinvestigator cannot reach agreement (or if any 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 <u>on behalf of the University, absent</u> <u>University approval of a transfer of the Research Data or Tangible Research Materials</u> 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 and must retain access to the Research Data or Tangible Research Materials and must retain access to the Research Data or Tangible Research Materials and must retain access to the Research Data or Tangible Research Materials and must retain access to 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

- University of California Regulation No. 4
- UC Copyright Ownership Policy
- UC Records Retention Schedule
- <u>Electronic Communications Policy</u>
- <u>Electronic Information Security Policy</u>
- 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
- <u>California Labor Code § 2860</u>

VII. FREQUENTLY ASKED QUESTIONS

Please refer to the attachment for Frequently Asked Questions. <u>Implementing guidance</u> related to this Policy may be posted on the UCOP Research Policy Analysis and <u>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

Frequently Asked Questions

1. Do Research Data include data generated by any non-University party?

Research Data do not include any results generated by any non-University party, unless and to the extent such results have been: 1) modified by a University Researchers within the course and scope of their assigned or assumed role while employed by the University; 2) generated using University Research Facilities; 3) transferred to the University by contract, grant or law; or 4) generated using funds provided by or received through the University.

University Research Facilities means University research premises or resources dedicated to research that (a) is provided by University for performing research, and (b) is more than only general campus facilities (e.g., libraries, meeting room) and ordinary business office facilities such as office work premises, telephone, or Internet access. However, situation in which individuals use an approved recharge facility/equipment on behalf of an external party who is/are paying an approved external user fee is outside the scope of the Policy. Please see FAQ #2 below for further information.

2. How does this Policy affect the work of University Research Facilities, such as Core Research Facilities, that provide services to those outside of the University?

Research Data created by or at the direction of University Researchers or Principal Investigators during the course of University Research remain the property of the Regents of the University of California, unless specifically agreed otherwise by the University under sponsorship or other related agreements. Research Data generated by or at the direction of non-University parties using University Research Facilities performing fee-for-service work or under specific University agreements fall outside the scope of this Policy.

3. Do Research Data include administrative records related to a research project?

Research Data do not include administrative records incidental to award administration such as financial records, contract and grant records, or records related to institutional reviews and approvals, such as IACUC or IRB review. While such administrative records generated by University researchers are not included in the definition of Research Data under this Policy, as records, they are the property of the University and may be subject to terms and conditions of individual sponsored projects, federal and state regulations, other University policies and University retention and disposition requirements. Information on retention requirements related to research administrative records can be found <u>here</u>.

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4. Under this Policy, do Research Data include data generated in the performance of a clinical trial or clinical research study including UC Health systems hospitals and outpatient clinics?

Clinical trial data generated by Researchers using University-administered research funding for clinical studies, regardless of where the information or material was generated (e.g., hospital or clinic), are considered Research Data under this Policy. Administrative documents, regardless of funding, such as patient source documents and medical records created in the course of clinical care are the property of the University along with other types of administrative records (see FAQ # 3 above) although they are not considered Research Data.

5. Do Research Data include scholarly works?

Research Data do not include scholarly works. Scholarly works has the same meaning as "Scholarly & Aesthetic Works" under the University of California's <u>Copyright Ownership Policy</u>. While the University of California Research Data Policy applies to all Research Data created during the course of University Research, unless specifically agreed otherwise by the University under sponsorship or other related agreements, it should not impede Researchers' ability to create scholarly works. This Policy also does not change current copyright and patent policies, which also apply to research.

6. Are Research Data stored on personal devices property of The Regents of the University of California?

Research Data are the property of The Regents of the University of California regardless of the medium or where the Research Data is collected or stored. This includes Research Data that is collected or stored on personal devices. Note, however, that each campus may have its own policies on the use of personal devices.

7. Does the transfer of Research Data to another institution allow for the continued use of University equipment or software programs?

Permission to transfer Research Data after separation by the Principal Investigator or any other Researcher does not imply a right to transfer or continue to use equipment or software programs used in connection with the research project. Permission to transfer or to continue to use equipment or software programs must be separately obtained from the applicable school, department, or center, and must be documented in accordance with campus requirements before any equipment or software programs may continue to be used or may be transferred.

8. Where can Researchers go to get help with managing and publishing Research Data?

UC campus and systemwide groups, including UC libraries, Research IT, and others provide extensive services and advice regarding data management, data

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publication, and data curation. Across the UC, there are unique offerings designed to meet the local needs of different research communities. Campus-specific and systemwide resources are available to help researchers manage Research Data effectively and meet the standards of funding organizations and the University.

These resources include:

- UC Berkeley
 - o Berkeley Research Data Portal
 - o Berkeley Research IT Research Data Management Program
 - o Berkeley Library Data Services Program
- UC Davis
 - o UC Davis Library Research Data Services
 - o UC Davis Library Data Management, Publishing, and Preservation
 - o UC Davis Health Research Data Management
- UC Irvine
 - o UCI Libraries Digital Scholarship Services
 - o UCI Libraries What We Do
- UCLA
 - o UCLA Library Data Management and Curation Services
 - UCLA Office of Research Administration Resources for Researchers
- UC Merced
 - o UC Merced Library Research Data Curation
- UC San Diego
 - UCSD Library Research Data Curation
- UC San Francisco
 - UCSF Library Data Management
 - <u>UCSF Data Resources</u>
 - o UCSF Data Resources: DMPTool
 - o UCSF Data Resources: Data Management
 - o UCSF Data Resources: Data Management Consultation
 - o UCSF Data Resources: Systems Services
 - UCSF Data Resources: Information Commons
 - o UCSF Data Resources: Library Data Science Initiative
 - <u>UCSF Data Resources: NLP@UCSF</u>
 - o UCSF Data Resources: Research Analysis Environment
 - o UCSF Data Resources: Research Electronic Data Capture (REDCap)
 - UCSF Data Resources: San Francisco Coordinating Center

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- UC Santa Barbara
 - o UCSB Library Research Data Services
- UC Santa Cruz
 - o UCSC Library Research Data Management
- California Digital Library:
 - All UC researchers have access to the <u>DMPTool</u>, which provides a wizard for creating an optimal data management plan that complies with funder requirements. The application also has direct links to funder policies, help text for answering questions, and resources for best practices surrounding research data management.
 - <u>Support Your Data</u> provides a framework for research data management best practices across a research project's lifecycle so to ensure optimal reuse of that data.
 - The University of California has a partnership with the multidisciplinary repository, <u>Dryad</u>, and all UC researchers may submit Research Data to be published, made publicly available, and archived at no cost.

9. Does posting Research Data to a repository comply with the policy to retain data?

Repositories are a great option for depositing data that may be made publicly available (or with restrictions). They also ensure long-term archiving and access to Research Data. Cloud-based services like Google Drive, Dropbox, Box, and AWS are not considered repositories and do not meet the requirements for long-term secure preservation of data.

Data that can be made publicly available should be submitted to an open data repository. If your field has standards around where data are held (e.g., NCBI repositories like Genbank), deposit your data in accordance with field best practices. If your field does not have standards around where data may be stored, use generalist data repositories. The University of California has a partnership with the generalist repository, Dryad, and all researchers may submit data to be publicly available and archived here at no cost. All UC datasets submitted to Dryad are also afforded long-term preservation in Merritt (UC's preservation repository). If Research Data have ethical and legal considerations, consult with your local IRB, IT security office, department, or other local offices on where the data may be held in a secure location.

10. How long should Research Data be preserved?

Recommended and required retention periods differ across disciplines, data types, funding agencies, applicable laws and regulations, and publishers. Researchers are encouraged to consult with a data librarian at their campus as well as other local and

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systemwide resources to determine if a recommended time period exists for Research Data.

11. Under what license should researchers share Research Data?

Research Data without ethical or legal restrictions may be made openly available under a CC0 license waiver. Refer to UC Office of Scholarly Communication's <u>blog</u> <u>post</u> for a detailed review of licensing options for data.

MODEL COMMUNICATION

The University of California Office of the President invites comments on a proposed Presidential Policy on University of California Research Data. This is the second systemwide review for this Policy. The first review of the Presidential Policy on the University of California Research Data and Tangible Research Materials was initiated on December 17, 2020 and closed April 7, 2021.

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 it is still in effect. The purpose of the new *Presidential Policy on University of California Research Data is to* 1) clarify ownership of and responsibility for research data generated during the course of University Research, 2) encourage active data management practices, and 3) provide guidance with respect to procedures when a research releaves the University.

If you have any questions or if you wish to	o comment, please contact	at
, no later than	, 2022	2.