



OFFICE OF THE VICE PRESIDENT - RESEARCH AND INNOVATION

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

December 17, 2020

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

Re: Systemwide Review of Proposed Presidential Policy University of California Research Data and Tangible Research Materials

Dear Colleagues:

Enclosed for systemwide review is the Presidential Policy on University of California Research Data and Tangible Research Materials.

The enclosed Presidential Policy University of California Research Data and Tangible Research Materials addresses issues concerning the ownership of data and tangible materials generated during the course of UC research. Over the past two years, the Research Policy Analysis and Coordination (RPAC) unit within the department of Research and Innovation at UC Office of the President met with a small advisory group made up of representatives from UCSD, UCLA, UC Berkeley, the Office of General Counsel, the California Digital Library, and several Academic Senate committees. The resulting draft policy states that the Regents of the University of California own Research Materials and Tangible Research Materials. The policy draft also calls upon campus leadership and its researchers to work in partnership to manage, retain, preserve, protect, access and share Research Data and Tangible Research Materials. For additional information on the points considered during the writing of this draft policy, please see attached materials.

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. Systemwide review also includes a mandatory, 90-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.

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We would appreciate receiving your comments no later than April 7, 2021. Please submit your comments to RPAC@ucop.edu with the subject line "Research Data and Tangible Research Materials Policy Comments." If you have any questions, please contact Agnes Balla at agnes.balla@ucop.edu or (510) 987-9987.

Sincerely,



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

Enclosures:

- 1) Presidential Policy University of California Research Data and Tangible Research Materials (clean copy)
- 2) Presidential Policy University of California Research Data and Tangible Research Materials Policy Points Considered
- 3) Model Communication

cc: President Drake

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Research Policy Manager Balla



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 applies to all Research Data and Tangible Research Materials generated by those at the University involved in the design, conduct, or reporting of research.

Contact:	Name
Title:	Title
Email:	Name@ucop.edu
Phone:	(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.

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.³ 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, [Chapter 1-520: Leadership of a Sponsored Project](#).

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.

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>

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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

DRAFT

UNIVERSITY OF CALIFORNIA DATA AND TANGIBLE RESEARCH MATERIALS POLICY POINTS CONSIDERED

Background

RPAC has been working on a policy document for some time that addresses issues concerning the ownership of research data and tangible research materials generated at UC. This has been an effort started, stalled, and stopped for many years, and in the interim both [UCSD](#) and [UCLA](#) issued Guidance on Access and Management of Research Data that closely resembles early drafts that RPAC worked on. Over the past year and a half, RPAC met with a small advisory group made up of representatives from UCSD, UCLA, Berkeley, the Office of General Counsel, and more recently CDL to better understand the issues at hand and to polish off the old data policy draft. The draft that was shared with several Academic Senate committees at the end of 2019 as a *preliminary* draft with the acknowledgement that there were certain aspects of the draft that could benefit from further discussion. The general feedback received during these meetings is that the draft tried to cover too much ground, including by imposing an unrealistic retention requirement for maintaining research data and tangible research materials, and thereby muddying the true intent of this policy.

Given this feedback, with the help colleagues at CDL, RPAC made revisions to the draft by staying focused on the question of who owns the data and materials generated during the course of research, in addition to better highlighting the value of research data and materials. The thought behind this is that we can address specific questions in subsequent implementing guidance. The list below details the discussions that had taken place to get the policy to its current state.

Resolved Issues:

- 1. Research Data and Tangible Research Material Retention:** The University has a detailed records retention schedule specific to administrative records. Research Data, however, are not included in that schedule. In fact, UC does not have a policy on the minimum length of time for which Research Data and Tangible Research Materials are to be retained. Early versions of the policy draft stated that Research Data and Tangible Research Materials must be maintained for a minimum of 6 years, with certain exceptions where data may need to be retained for longer. The policy did not include a provision for who may approve earlier destruction or removal, and whether that is a campus or case-by-case decision.

Resolution: After discussions with several groups (VCRs, UCORP, SLASIAC, CoUL, and others) in late 2019 about the initial policy draft, it was stressed that the cost (both financially and administratively) to maintain Research Data and Tangible Research Materials is significant and in some cases would not make sense (e.g., while researchers may keep data from collected blood samples, they may not keep the blood sample itself due to its cost to keep it in the fridge; researchers may keep notes from interviews but not the video of the interview itself). Thus, this iteration of the draft policy does not state a minimum length of time for which all Research Data and Tangible Research Materials must be retained. Rather, the policy explains that 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. The policy also points out cases where retention periods may need to be longer.

- 2. Transfer of Research Data or Tangible Research Materials to Another Institution:** The draft policy states that the University will always retain ownership of original Research Data and Tangible

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Research Materials even if the Principal Investigator or the research is transferred to another institution, but on a case-by-case basis, the campus may allow for the transfer of original Research Data or Tangible Research Materials to another institution in such situations.

Resolution: We did not describe whether there is an expectation for a formal agreement with the new institution, such as an MTA, DUA or other agreement. We left this open so that the campus has flexibility to manage this on a case-by-case basis. For example, for a small project, a campus may only require an email acknowledgement from the institution receiving the data or materials; however, for a major research project, there may be a need for a formal contractual arrangement.

- 3. Common Data Identifiers and Data Management Plans:** If UC will be requiring the retention of Research Data, it would be beneficial if that data is retained in a usable format, such as with common data identifiers or specified data management plans. Should this policy encourage/require the use of data management plans or common data identifiers?

Resolution: The policy now states that 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. We discussed that should further resources be helpful on this point, we can address them in subsequent policy guidance.

- 4. Copyright Policy:** The initial draft of the data policy included “Scholarly Works” as part of the definition of Research Data so to only point out that “Scholarly Works” is not included in the definition of Research Data.

Resolution: In the current iteration, the term “Scholarly Works” is not included in the definition of Research Data. This issue is instead addressed with an FAQ question.

- 5. Use of personal devices for research purposes:** What is UC’s stance on Research Data and Tangible Research Materials collected and stored on personal devices?

Resolution: We addressed this point with an FAQ at the end.

- 6. Publication of Research Data:** The question came up of whether this policy should address the issue of research collaborators, graduate students or others working on a Principal Investigator’s project who publish data ahead the Principal Investigator or without the Principal Investigator’s consent.

Resolution: This iteration of the draft is silent on addressing this issue, but we discussed several ways in which we can try to tackle the issue in the policy. For example, we one way to tackle this issue is to include a bullet under University Employee Responsibilities that states the requirement to confer with the Principal Investigator about the use of Research Data generated under a research project to ensure that there are no independent publications prior to first publication by the Principal Investigator. However, there was debate as to what happens if a lower level researcher does not agree with a Principal Investigator?; would a Principal Investigator need to confirm with all the collaborators (a term not defined in the policy) before they can publish or re-use the data?; what would the agreement need to look like?; What criteria can the Principal Investigator use to fairly deny the request? Another way to try to address this issue is to support mutual agreement between a Principal Investigator and collaborators on how and when and by

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whom the research data may be released/published/shared (such as by including a statement about securing agreement among all research collaborators in regard to data use, sharing, and reuse.) Ultimately, it seemed like the issue of publication was outside the scope of this policy and should not be addressed in this policy. In addition, in trying to come up with the right approach to address the issue seems to counter the main intent of this policy, that the Regents own Research Data and efforts to arbitrarily resist or delay use Research Data for critical University purposes flies in the face of the policy.

Frequently Asked Questions

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

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

2. 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 [here](#).

3. The UC Health systems hospitals and outpatient clinics have not traditionally been considered “research facilities or research resources.” Under this Policy, do Research Data and Tangible Research Materials include data and materials generated in the performance of a clinical trial or clinical research study?

Clinical trial data and materials generated by Workforce Members using University-administered research funding for the clinical trial, regardless of where the information or material was generated (e.g., hospital or clinic), are considered Research Data and Tangible Research Materials under this Policy, respectively. However, administrative documents, regardless of funding, such as patient source documents and medical records created in the course of clinical care are not considered Research Data, but are the property of the University along with other types of administrative records (see FAQ # 2 above).

4. Do Research Data include scholarly works?

Research Data do not include scholarly works. Scholarly works has the same meaning as “Scholarly & Aesthetic Works” (or the term most closely analogous to “Scholarly & Aesthetic Works”) in the University of California’s Copyright Ownership Policy. While this Policy applies to all Research Data and Tangible Research Materials generated by Workforce Members involved in the design, conduct, or reporting of research, it should not impede Workforce Members’ ability to create scholarly works nor change current copyright and patent policies, which also apply to research.

Frequently Asked Questions

5. Are biospecimens (e.g., remnant blood or tissue samples, etc.) collected from University patients in the course of clinical research considered Tangible Research Materials under this Policy?

Biospecimens collected or used for research: (1) within the course and scope of a Workforce Member's assigned or assumed duties; (2) using University research facilities or other University resources; or (3) with support from or through the University are considered Tangible Research Materials under this Policy. The collection and use of human biospecimens for research requires review by an IRB and may require other campus compliance review in accordance with local campus and hospital policies.

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 ownership 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