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| |  |  |  | | --- | --- | --- | | |  | | --- | | **Policy Title: Research Data and Materials Policy** | | Policy Administrator: Academic Affairs - ORIED Authority: Effective Date: when President signs the policy - leave blank Updated:  Index Cross-References: EO 890, EO 1031, Patent and Copyright Policy, Research Integrity Policy Policy File Number: | | | **RESEARCH DATA AND MATERIALS POLICY**  **Definitions:**   1. **Co-Investigator**   This title designates key personnel for a project, but without the oversight responsibility of a PI.   1. **Co-Principal Investigator**   This designation refers to individuals who share the responsibility for the project with the PI.   1. **Data Manager**   **In accordance with EO 1031 and the campus delegation of authority, the Principal Investigator is designated as the Data Manager of research data created with Sacramento State resources.**   1. **Data Owner**   **In accordance with EO 1031 and the President’s Delegation of Authority to Data Owners, the Associate Vice President for the Offices of Research, Innovation, and Economic Development is designated as the Data Owner of research data created with Sacramento State resources.**   1. **Principal Investigator**   The principal investigator (PI) is the individual (or in the case of co-principal investigators, the individuals) directly responsible for the overall design and conduct of a research project and is accountable to the University, and to external sponsors if any, for the proper programmatic, scientific, or technical conduct of the project, and its financial and day-to-day management. For sponsored projects administered by University Enterprises, Inc. (UEI), this role is designated by the UEI Director of Sponsored Programs Administration and approved by the sponsor to direct a project funded by the external sponsor. For research conducted by students, this role is generally vested in the faculty advisor.   * The PI is ultimately responsible for the data used and generated in the project, and is responsible for managing research data and materials in accordance with the principles and requirements outlined in this policy. The PI may choose to delegate the management responsibility of the data and materials to a co-investigator of the project. * Where research is conducted in collaboration with external research partners, responsibility for the management of data and materials for the project is still held by a Sacramento State University PI, co-investigator, or delegate. * The PI is responsible for ensuring continuity of the data and materials management and, should the PI leave the university or end association with the project, is responsible for making appropriate arrangements for the data and materials at the end of the project.  1. **Research**   A systematic study intended to increase knowledge or understanding of the subject studied; a systematic study specifically directed toward applying new knowledge to meet a recognized need; or a systematic application of knowledge to the production of useful materials, devices, and systems or methods.   1. **Research Data**   The recorded factual material commonly accepted in the scientific community as necessary to validate research findings, including, but not limited to, all records necessary for the reconstruction and evaluation of the results of research, regardless of the form or medium on which the material is recorded (such as lab notebooks, photos, digital images, data files, data processing or computer programs (software), statistical records, etc.).  Research data does not include books, funder reports, articles, papers, or other scholarly writings that are published or publicly presented; drafts of such scholarly writings; preliminary analyses; plans for future research; peer reviews; or communications with colleagues.   1. **Research Data Management**   All research requires some level of data management before, during, and subsequent to the active research period. “Research data management” refers to the actions researchers take before, during, and after a research project that involve data; from planning, to creating, organizing, securing, sharing, and looking after the data, and the documentation they keep about these actions.   1. **Research Materials**   Tangible items that are the product of research or that are used to conduct research. Examples of research materials include reagents, cell lines, plasmids, vectors, chemical compounds, and some kinds of devices and software.   1. **Sacramento State Researcher**   A Sacramento State faculty member, staff member, or student or UEI personnel who generates research data or materials with the support of Sacramento State resources.   1. **Sacramento State Resources**   Sacramento State funds (including, for example, sponsored awards administered by UEI), salaries, gifts, endowment funds, and travel grants), facilities, staff, or equipment.  **Why the Policy is necessary:**  As part of its strategic goals, Sacramento State is committed to fostering innovative teaching, scholarship, and research. The University deems appropriate stewardship of research data as fundamental to both high-quality research and academic integrity and therefore seeks to attain the highest standards in the generation, management, retention, preservation, curation, and sharing of research data.  Sacramento State has an obligation to ensure that its resources are used appropriately and that research conducted at Sacramento State meets standards of integrity imposed by the Office of Research Integrity, The Office of Management and Budget Guidance for Grants and Agreements (2 CFR 200), and California State University Executive Order 1031 for systemwide records information retention and disposition schedules. Sacramento State also has rights and obligations regarding the dissemination and commercialization of knowledge resulting from research conducted with Sacramento State resources. Federal agencies, including the National Institutes of Health and the National Science Foundation, among others, have expectations of grantees for providing public access to research data and materials, notably policies for data sharing, management and public accessibility to published results. In order to meet its obligations and protect its rights, the University must ensure that original research data and materials are secure and appropriately accessible.  By relying on established principles for determining the ownership of research data and materials the University seeks to avoid and resolve disputes so that disagreements over ownership need not impede research or Sacramento State’s mission for the dissemination of new knowledge.  **Policy Statement:**  Sacramento State researchers are data managers of research materials and data generated with the support of Sacramento State resources. Sacramento State researchers have the academic freedom to determine the course and publication of any research, subject to legal requirements, Sacramento State policy, ethical standards, and the terms and conditions of sponsored awards. The data owner of research data and materials for projects conducted with Sacramento State resources is the Associate Vice President for the Offices of Research, Innovation, and Economic Development.  Sacramento State’s ownership and stewardship of research data and materials for projects conducted at the University, under the auspices of the University, or with University resources are based on both regulation and sound management principles and is in support of its mission of outstanding research and scholarship, education, preservation and practice, and the free exchange of ideas.  Research data and materials that are commonly accepted in the scientific community as necessary to validate research findings must be retained by Sacramento State researchers for three (3) years after final publication of the findings or until all required final reports (e.g., progress and financial) for the project have been submitted to the sponsor, unless a longer period is provisioned. Principal Investigators (PIs) or co-Principal Investigators (co-PIs) have a right to access and may generally take copies of the data when they leave Sacramento State. Other co-investigators involved in the creation of research data may access and take copies of research data for projects (or the portions of projects) on which they have worked with the permission of the PI or PIs. Sharing of research data and materials that are commonly accepted in the scientific community as necessary to validate research findings with members of the University community, external collaborators, and others for legitimate purposes, is encouraged, often required by law, and subject to Sacramento State policy and to legislative, regulatory, contractual, ethical or other obligations.  **Who the Policy applies to:**  This policy applies to all research data and materials generated with the support of Sacramento State resources, and it applies to all Sacramento State faculty members, staff members, students, UEI personnel, consultants and any others involved in the design, conduct or reporting of research. The policy does not change current copyright, patent, and record retention policies that also apply to research.  **Responsibilities:**   1. **Researcher/Data Manager**   In their role as managers of research data and materials, and in keeping with academic practice, Sacramento State researchers are responsible for:   * Recording, collecting, managing, retaining, and sharing research data and materials according to legal requirements, Sacramento State policy, and the terms and conditions of sponsored awards. * Ensuring the retention of original data and materials. * Where research involves the use of data owned by a third party, abiding by licenses or terms of use governing that data.  1. **Sacramento State University/ Data Owner**   Sacramento State’s responsibilities include but are not limited to:   * Protecting the rights of Sacramento State Researchers as provided in this policy including, but not limited to, their right to academic freedom, rights to access data from research in which they participated, and rights to take copies of their data when they leave the University. * Developing and implementing compliance systems, consistent with applicable legal requirements, to address scientific misconduct and conflict of interest. * The University is accountable to sponsors for meeting all obligations concerning research data, and for supporting an environment in which the objectives of its policies and principles are met.   **Procedure:**   1. Ownership   Sacramento State’s ownership and stewardship of research data and materials for projects conducted at the University, under the auspices of the University, or with University resources are based on both regulation and sound management principles and apply in all cases except where precluded by the specific terms of sponsorship or other agreements.  Similarly, any intellectual property rights in research data and related materials shall remain with the University unless otherwise specified by law or in a duly executed agreement. The Sacramento State [Copyright Policy](https://www.csus.edu/umanual/acad/umc02750.htm) provides that generally, books, articles and other scholarly writings by a faculty member are deemed the property of the writer, who is considered to be entitled to determine how the works are to be disseminated and to keep any income they produce, unless otherwise provided by law.   1. Retention   Generally, and in accordance with 2 CFR 200, research data and materials that are commonly accepted in the scientific community as necessary to validate research findings must be retained by Sacramento State researchers for three (3) years after publication of the findings or all required final reports (e.g., progress and financial) for the project have been submitted to the sponsor.  Longer retention periods may be required by Sacramento State policy, publishers, sponsors, and applicable law. Sacramento State researchers are responsible for consulting those requirements and research data must be retained in accordance with those more stringent requirements. Some key provisions and circumstances are as follows:   * Research data must be kept until any patentable invention resulting from the work is protected by the filing of a patent application or, if a decision is made by the University not to file for patent protection, until rights to the invention are returned to the inventor. * If charges of academic misconduct or conflict of interest have been made in relation to a research project, the research data must be retained by the University as long as required by any sponsoring agency’s requirements, but at least until all charges have been resolved and final action taken. If the research data were the subject of litigation or investigation, the research data must be retained for seven (7) years or until the Office of the General Counsel has issued instructions regarding their disposition, whichever is later. * Research data involving human subjects presents special requirements. Sacramento State researchers must consult University policy as well as federal and state laws and regulations related to research data retention, as applicable. * If a student is involved in a non-externally funded research project, the research data must be retained until the student has been awarded a degree or it is clear that the student has abandoned the work. Externally funded research data must be retained by the Faculty Advisor for a minimum of three (3) years after publication of the findings or all required final reports (e.g., progress and financial) for the project have been submitted to the sponsor. Students have a right to take copies of their research data upon graduation. * If the research data or materials are appraised by the University to have long term cultural, historical, economic, environmental, or other acknowledged value, then the University may require a longer retention period. * If the research project involves FDA regulated articles, then, consistent with 21 C.F.R. §§ [312.6](https://www.gpo.gov/fdsys/granule/CFR-2012-title21-vol5/CFR-2012-title21-vol5-sec312-6) and [812.140](https://www.gpo.gov/fdsys/granule/CFR-2012-title21-vol8/CFR-2012-title21-vol8-sec812-140), the investigator 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. If other regulations, sponsor policies, or guidelines require longer retention periods, research data must be kept in accordance with those more stringent requirements.  1. Transfer   When Sacramento State researchers who are PIs or co-PIs on research projects at Sacramento State leave the University, they may generally take copies of research data for projects on which they have worked. Taking copies of data or materials subject to confidentiality or other legal restrictions, including but not limited to data and materials that are covered by human subjects protections, export controls, relevant to disputes and investigations, or necessary for patent protection, may be restricted and requires permission from Sacramento State.  Other co-investigators may take copies of research data for projects (or the portions of projects) on which they have worked only with the permission of the PI or PIs or, if the PI or PIs and the individual leaving cannot reach agreement, with the permission of Sacramento State. In all cases, the original data and materials must be retained at Sacramento State.  In appropriate circumstances, Sacramento State may transfer ownership of research data or materials to a third party pursuant to a duly executed sponsored award or other agreement.  For data, the transfer of ownership from Sacramento State to another institution requires prior written approval from Sacramento State. It will generally be granted only when the research project itself is being transferred to the other institution and will be pursuant, at a minimum, to a written agreement executed by the recipient institution that guarantees (1) its acceptance of ongoing management responsibilities for the data, and (2) Sacramento State having access to the original data, should access become necessary for any reason. The transfer will be in accordance with relevant confidentiality restrictions, when Sacramento State deems them appropriate or necessary or as required by law. For materials, transfer requires execution of a material transfer agreement (MTA) executed by Sacramento State and the recipient institution prior to the removal of the materials or equipment from the University premises.   1. Sharing and Access   Sharing of research data and materials that are commonly accepted in the scientific community as necessary to validate research findings with members of the University community, external collaborators, and others for legitimate purposes, is a key precept of the University.  Research data and materials shall be made publicly available to the extent feasible while minimizing harm to the legitimate interests of the University, to research subjects, and to other parties, subject to Sacramento State policy and to legislative, regulatory, contractual, ethical or other obligations, including but not limited to whether providing such public access would be cost prohibitive.  Where necessary to assure needed and appropriate access, the University has the option to take custody and management of the data in a manner specified by ORIED. For example, if charges of academic misconduct or conflict of interest have been made in relation to a research project.  Sacramento State researchers who are PIs or co-PIs on research projects at Sacramento State have a right to access research data for projects on which they have worked. Other co-investigators may access research data for projects (or the portions of projects) on which they have worked only with the permission of the PI or PIs or, if the PI or PIs and the individual leaving cannot reach agreement, with the permission of Sacramento State.  Please review the Research Data Guidance on the Offices of Research, Innovation, and Economic Development’s website for more details regarding procedures.  **Approved by:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Robert S. Nelsen, President** | |

This policy is based on the *Research Data & Materials Policy* from Yale’s Office of Provost for Research accessed on 1/13/2020.