Interim UCLA Guidance on Access to and Management of Research Data and Tangible Research Materials

I. Purpose

The collection and generation of data and tangible research materials is an integral part of any research project. Accurate and appropriately recorded research data, and the creation and retention of tangible research materials, enable scholars to report, replicate, and refute research findings, which ultimately advances the research enterprise. The University, its faculty, staff and trainees have legal, institutional and ethical obligations to manage and retain such records of research conducted at the University. Both the University and researchers also have responsibilities concerning access to, use of, and maintenance of research data and research materials.

These obligations are not new and are not unique to the University; they arise from express provisions in awards and agreements with federal and other research sponsors, overarching regulatory requirements relating to funded research, and fundamental precepts of research integrity. University access to records of research is critical for oversight purposes, such as responding to audits, establishing that past use of University or research sponsor funds was appropriate, responding to government demands or subpoenas, defending research findings, facilitating research misconduct proceedings, and facilitating proper conduct of research with humans or animals.

This guidance is designed to ensure that Research Data and Tangible Research Materials, as defined below, are appropriately documented, maintained, retained for a reasonable time, and accessible to the University and the research community for review and use.

II. Scope and Administration of the Policy

This guidance applies to all UCLA employed or affiliated academic personnel, staff, and trainees, engaged in research or research-related activities at the University of California, regardless of the funding source of such activities. This guidance may also apply to students and non-University employees conducting any research using University research funds, resources, or facilities and/or in collaboration with individuals with University appointments.

The Vice Chancellor for Research or his/her designee(s) is responsible for the oversight, interpretation and implementation of this guidance.

III. Definitions

- a. "Principal Investigator": For the purposes of this guidance, the "Principal Investigator" is the individual who personally participates and has primary responsibility for the design, conduct and administration of a research project, regardless of the source of funding or status of that project.¹
- b. "Research Data" are recorded information reflecting original observations and methods related to a research study, and documentation of such data needed to reconstruct and evaluate reported results of the study, regardless of the form or medium on which it may be recorded,.² As used in this guidance document, Research Data encompasses such data that is produced: (i) within a University researcher's course and scope of employment; (ii) using University research facilities or other research resources; or (iii) using funds provided by or through the University. Research Data further includes such data in any format or medium, such as computer software, databases, and data of a scientific or technical nature, including laboratory notebooks, field notes, electronic storage media, and printouts. Research Data also include "Tangible Research Material", as defined below. Research Data do not include administrative records incidental to award administration such as financial records, contract and grant records, etc. While such administrative records generated by University researchers are not included in the definition of Research Data under this guidance, they are the property of the University and may be subject to terms and conditions of individual sponsored projects, federal and state regulations, and University retention and disposition requirements.
- c. "Tangible Research Material" is a tangible item produced or collected in the course of research: (i) within a University researcher's course and scope of employment; (ii) using University research facilities or other research resources; or (iii) using funds provided by or through the University. Tangible Research Material includes, but is not limited to, biological specimens, environmental samples, devices, prototypes, circuits, chemical compounds, genetically engineered organisms, cell lines, cell products, viruses, genetic material, plants, and animals.

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

² Other research data may be obtained through 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.

IV. Ownership and Stewardship of Research Data and Tangible Research Materials

Research Data are the property of The Regents of the University of California.³ The Principal Investigator shall retain Research Data on behalf of the University, in accordance with Section VI.b. of this guidance. The Principal Investigator is responsible for ensuring that Research Data, whether generated by the Principal Investigator or the Principal Investigator's research team, are recorded, stored, and used in accordance within the standards of his or her respective discipline, campus department, and any requirements of applicable federal or state law or regulations, University policies and guidelines, and University contractual commitments.⁴

The Principal Investigator shall consult the Office of the Vice Chancellor for Research or other appropriate campus office regarding the use and stewardship of Research Data and Tangible Research Materials that may be subject to applicable export control regulations, laws and regulations protecting the rights and privacy of human subjects. This includes but is not limited to, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), or other applicable laws and regulations.

V. Sharing of Final Research Data and Tangible Research Materials

UCLA supports the sharing of Research Data to advance public knowledge. In the interest of advancing knowledge, the University expects Principal Investigators to publish, release, and share final Research Data. Specifically, final Research Data should include the Research Data necessary to document and support research findings. Final Research Data should be made available for use by other researchers within the University and outside the University in a timely manner, consistent with the current practices of the discipline involved, and in accordance with existing University policies and guidelines, including those related to intellectual property, sponsor requirements, and applicable laws and regulations, such as laws relating to protecting the rights and privacy of human subjects. The National Institutes of Health policies on data sharing and sharing of biomedical research resources (http://grants.nih.gov/grants/policy/data_sharing/) and the National Science Foundation Policy on Dissemination and Sharing of Research Results (http://www.nsf.gov/pubs/policydocs/pappguide/nsf11001/aag_6.jsp#VID4) are models that investigators may find useful when planning for the sharing of Research Data.

³ <u>University of California Regulation No. 4</u> (APM-020) provides that original records of the research are the property of the University. ("Original records" may include tangible records of research, such as biological materials, chemical compounds, plants, etc.). 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. (See also: Ownership of Administrative Records, Oct. 31, 1969).

⁴ Contract and Grant Manual, <u>Chapter 10-330: Principal Investigators</u>.

In all instances, Principal Investigators should consult relevant award and/or agreement terms to determine whether final Research Data are subject to any special handling, use or restriction terms.

VI. Access to and Transfer of Research Data and Tangible Research Materials

a. University Responsibilities

- i. In most research contracts and grants, the University has committed to the sponsor that it will retain Research Data and make it available as appropriate.
- ii. Research agreements and clinical trial agreements with industry sponsors and other funding entities require careful negotiations to avoid placing restrictions on the University's access to, use of, and dissemination of Research Data.⁵
- iii. The University shall protect the ability of its affiliated academic personnel, students, postdoctoral scholars, and staff to access and use the Research Data from research in which they participated.⁶
- iv. The stewardship and storage of Research Data Materials shall be discussed and resolved with the Vice Chancellor for Research, or his designee, as part of the exit process when a Principal Investigator leaves the University to ensure that Research Data and Tangible Research Materials continue to be accessible to the University in accordance with this guidance.

b. Principal Investigator Rights and Responsibilities

In general, Principal Investigators shall retain all Research Data on behalf of the University in accordance with this Guidance for as long as possible, but not less than a minimum of six years after final reporting, publication, completion or abandonment of the project, unless a longer retention period is indicated by the funding source or other relevant agreement. ⁷, ⁸ The University may require a longer retention period to comply with applicable laws or regulations, support

⁵ <u>Principles Regarding Future Research Results: Open Dissemination of Research Results and Information; Senate Concurrent Resolution (SCR) 66: Postsecondary education, academic research "gag clauses".</u>

⁶ Principles Regarding Future Research Results: Accessibility for Research Purposes.

⁷ Contract and Grant Manual, Chapter 17-310: Records Disposition Schedules for Contract and Grant Documents; Administrative Records Relating to Research: Retention Requirements (last updated June 2010).

⁸ Storage in a repository may not necessarily satisfy the obligations set forth in this guidance, applicable laws and regulations, or the relevant agreement.

patent or intellectual property claims, or perform any necessary investigations associated with allegations of research misconduct. If a student is involved, Research Data must be retained at least until the student's degree is awarded or it is clear that the student has abandoned the work.

Research Data may not be destroyed while an audit, research misconduct inquiry, investigation, public records request, or legal action involving such Research Data is pending.

i. If a co-investigator, student, trainee, or other member of a research team leaves the University, all Research Data, including laboratory notebooks, and Tangible Research Materials must be left with the Principal Investigator. Unless applicable laws, regulations or the relevant agreement so prohibit, the departing researcher may take copies of Research Data for projects on which they have worked in accordance with this guidance.

A co-investigator, student, trainee, or other member of a research team may not independently publish Research Data prior to first publication by the Principal Investigator without the written consent of the Principal Investigator. This should not be construed to prevent students from filing a copy of their dissertations or theses as required by their schools or departments, including depositing copies of their theses in archives as may be required by their schools or departments.

ii. Unless applicable laws, regulations or the relevant agreement so prohibit, a departing Principal Investigator may take copies of Research Data produced by him or her or under his or her direction while at the University when he or she leaves the University. Copies of Research Data containing personally identifiable health information of patients or subjects may not be taken except pursuant to applicable laws, regulations and consistent with University policies.¹⁰

Original Research Data may be transferred to another University campus or other institution only with approval of the Vice Chancellor for Research or his/her designee, generally under a written consent between the University and departing Principal Investigator. In all cases, the University reserves the right to access the original Research Data.

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⁹ However, in the interest of promoting academic freedom, schools or departments may consider exceptions to the guidance requiring the written consent of the Principal Investigator in the event a co-investigator seeks to publish Research Data.

¹⁰ Contract and Grant Manual, Chapter 18-272: Records Retention, Inspection and Copying (Protection of Human Subjects in Research).

iii. When a Principal Investigator leaves the University, tangible Research Materials shall remain at the University. Subject to any third-party restrictions, Tangible Research Materials may be transferred to a departing Principal Investigator only with the written approval of the Vice Chancellor for Research or his/her designee, generally under a material transfer agreement between the University and the Principal generally under a material transfer agreement between the University and the Principal investigator's new employer.