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 <u>UCSD</u> and <u>UCLA</u> 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

UNIVERSITY OF CALIFORNIA DATA AND TANGIBLE RESEARCH MATERIALS POLICY POINTS CONSIDERED

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 reuse 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

UNIVERSITY OF CALIFORNIA DATA AND TANGIBLE RESEARCH MATERIALS POLICY POINTS CONSIDERED

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