Guidance on Putting Data Disposition/Destruction Dates in Human Subjects Research (HSR) Protocols and Informed Consent Forms

Human Subjects Research Data Ownership

Research data, including all data collected from or about human subjects, at the University of California is owned by the Regents of the University of California (<u>University Regulation 4</u>). Under Regulation 4, faculty researchers at the University of California are considered the primary stewards of the research data, and thus have authority over and responsibility for storage, maintenance, and other definitive decisions about the data, including when to destroy or dispose of no longer useful data sets that were collected in the course of research.

Human Subjects Research Data Destruction/Disposition

While HSR data and Personally Identifiable Information (PII) may be required to be stored and secured in a certain way (please see https://it.ucmerced.edu/security-policies/what-kind-of-data-can-i-store-on-box/), at this time there are no federal, state, or University regulations that require the destruction of academic HSR data at a certain point in time after collection. Records obtained or loaned from the California Department of Public Health (birth records, death records, disease registers, etc.) are not considered research data and may be required to be destroyed after the research is completed. These records are owned by the State of California, not by the Regents, and thus are not subject to UC policy. Language regarding disposition or destruction of these kinds of state records may be in protocols and consent forms.

The UC Merced IRB cautions researchers against providing specific HSR data destruction/disposition dates in HSR protocols, or in HSR informed consent forms. By specifying dates or maximum storage times, researchers commit themselves to a specific action and deadline that, years after data collection, may not be met. This may result in findings of noncompliance and potential complaints from participants in the studies, should they be informed that the data has not been destroyed as stated.

The UC Merced IRB recognizes that research sponsors, contract partners, journals, and even professional societies, may impose *minimum* storage and maintenance times on HSR data. This is acceptable. As yet, these entities have not imposed *maximum or limited* HSR data storage times.

Please contact the UC Merced IRB directly if you propose to include specific HSR data destruction/disposition dates in HSR protocols and/or in informed consent forms. The IRB can provide general language to use in informed consent forms which meets the responsibilities of the University and complies with any federal, state, or institutional policies that may apply.

This guidance applies to HSR data only, and does not apply to HSR administrative records, such as informed consent forms or protocol forms. For information on HSR administrative

records retention and disposition, please see (http://www.ucop.edu/research-graduate-studies/ files/research/policies/documents/retention_disposition_reqs.pdf).

For questions about this guidance, or about HSR data destruction or disposition, please contact: irboffice@ucmerced.edu.