COLUMBIA UNIVERSITY

Guidance on Retention of Research Data

I.   Introduction

Maintaining accurate and appropriate records with respect to original Research Data (as such term and certain other capitalized terms used herein are defined in Section III(A)) is an essential component of any research project. It is necessary to support and substantiate findings, to protect intellectual property rights, to facilitate management of the research program of Columbia University (the **University)**, to enable data sharing and to ensure compliance with federal regulations, University policies and sponsor requirements.

Best practices with respect to the maintenance and retention of research records depend on the nature of the research, the data generated and the standards of the discipline. Therefore, this Guidance sets forth only certain general principles that govern the retention of Research Data.

Individual schools, departments or centers of the University may supplement this Guidance by developing policies applicable to research conducted in such school, department or center. In such supplements, individual schools, departments or centers may expand the definition of Research Data and may otherwise impose such rights and restrictions as are reasonably necessary, provided that any such supplement must be consistent with the principles articulated in this Guidance. Finally, standards, technology and requirements for Research Data retention are rapidly evolving. Accordingly, this Guidance will be updated as needed in response to changes.

This Guidance applies to all University faculty, staff, students and other persons at the University involved in the design, conduct or reporting of research conducted at or under the auspices of the University (**University Research)** and applies to all research projects in which those individuals participate, regardless of the source of funding for the project.

The University has established a central website called Research Data at Columbia University, at https://research.columbia.edu/research-data-columbia, that provides links to many University resources for research data management. Links to relevant regulations and other relevant University policies referred to in this Guidance can be found in Appendix A hereto.

Questions on the interpretation of this Guidance may be directed to the Office of the Executive Vice President for Research (**EVPR**).

II.   Effective Data and Scope

The effective date of this Guidance is October 20, 2017.

This Guidance does not supersede the **University Records Retention Policy**, effective as of May, 2011, as amended (the **University Records Retention Policy**), and the **Sponsored Projects Administration Policy on Records Retention,** effective as of May 2011, as amended (the **SPA Records Retention Policy**), issued pursuant to the University Records Retention Policy.

III.   Guidance Text

A.   Definitions

As used in this Guidance, certain terms are defined as follows:

PI: as defined in Section III(C).

EVPR: as defined in Section I.

Information Security Charter: as defined in Section III(E).

Research Data: any recorded information that is commonly accepted in the relevant research community as embodying the facts resulting from the applicable University Research inquiry or is necessary for the reconstruction and validation of results of University Research and the events and processes leading to those results, regardless of the form or the media in which they may be recorded. Research data include both intangible data (e.g., statistics, findings, formulas, etc.) and physical and digital data (e.g., notebooks, protocols, case history records, etc.).

SPA Records Retention Policy: as defined in Section II.

University: as defined in Section I.

University Research: as defined in Section I.

B. Reasons for the Retention of Research Data

It is important that investigators have the ability to document the results of University Research both for the sake of the scientific enterprise and to ensure that the investigator and the University meet their scholarly and legal requirements, including (1) substantiating grant applications, justifying the use of research funds or demonstrating compliance with grant or contract terms; (2) supporting published research findings; (3) meeting public access requirements, (4) supporting any intellectual property or patents resulting from research; and (5) safeguarding scholarship that should be considered for long-term preservation and access.

C. Ownership of Research Data

Research Data and other records of University Research belong to the University, except in the unusual instance when such ownership is precluded by the specific terms of a sponsorship or

other agreement. Both the University and the principal investigator (**PI)** have rights and responsibilities with respect to access to, and use and maintenance of, original Research Data.

See also the University's **Statement of Policy on Proprietary Rights in the Intellectual Products of Faculty Activity**, which provides that unless it has specifically waived its rights, the University holds the intellectual property rights to patentable inventions and discoveries and any associated technology that result primarily from the use of its facilities or from the activity of its officers while engaged in its service.

D. Responsibilities

1. University Responsibilities

The University has the following general responsibilities with respect to the retention of Research Data:

- Complying with regulatory requirements with respect to the retention of Research Data to support grant or contract payments;
- Complying with the terms of sponsored project awards or agreements;
- Protecting the ability of students, postdoctoral appointees, staff and other collaborators to access data from research in which they participated;
- Securing the University's intellectual property rights; and
- Sequestering or otherwise obtaining access to Research Data for a required investigation pursuant to University policy and/or regulatory or sponsor requirements.

2. PI Responsibilities

The PI has the following responsibilities[1] with respect to the retention of Research Data:

- Identifying, collecting, managing and retaining Research Data as custodian for the University;
- Ensuring that sufficient records are kept to document the experimental methods and accuracy of data collection as well as the methods and accuracy of data interpretation;
- Adopting an orderly and dated system of Research Data organization;
- Communicating the chosen system of data organization to all members of his/her research team, including appropriate administrative personnel;
- Complying with sponsor requirements regarding data access and retention; and
- Complying with the University's rules on the ownership of data associated with inventions or tangible research property that the University wishes to commercialize.

E. Retention of Research Data

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[1] Investigators must also document the administrative and financial management of research as set forth in the SPA Records Retention Policy.

Retention of Research Data is not only critical to substantiate results, but also to provide a foundation for the advancement of scholarship. At times, new research may build upon data collected at a time before the importance of such data could have been envisioned. For this reason, this Guidance encourages retention of Research Data for an unlimited time period when feasible. At a minimum, however, Research Data should be retained, generally, for three years after the end of a research project, or if longer, the period required by the applicable sponsor, with original Data retained wherever possible. For this purpose, a research project should be regarded as having ended after the latest of (1) final reporting to the research sponsor; (2) final financial close-out of a sponsored research award; (3) final publication of research results; or (4) cessation of an academic or research project, regardless of whether its results are published. Individual schools, departments or centers may establish a longer, but not a shorter, period of retention.

Regardless of the policies adopted by a school, department or center, the following circumstances may require longer retention periods:

- Data that must be kept for as long as necessary to protect intellectual property and complete patenting and licensing procedures for inventions resulting from University Research;
- If any charges regarding the research arise, such as allegations of scientific misconduct or improper charging of costs, data must be retained at least until such charges are fully resolved or for such other period as may be required by University policy or regulation; and
- If a student is involved in the research, data must be retained for at least three years afterl the student's degree is awarded or it is clear that the student has abandoned work on the project.

Research Data records will normally be retained by the PI in the school, department or center where they were produced. Some disciplines have established public or private data centers or repositories in which Research Data are expected to be deposited. The University encourages the submission of Data to the appropriate data center or repository.

Note that the storage of electronic Research Data is governed by the **Columbia University Information Security Charter** (the **Information Security Charter)** and the other Information Security Policies referred to in such Charter.

The following are not required to be retained under this Guidance:

- Duplicates of original records;
- Preliminary draft of letters, memoranda, reports, worksheets and informal notes that do not represent significant steps and/or decisions in the preparation of the original records;
- Books, periodicals, manuals, training binders, newspapers and other printed material obtained from external sources and retained primarily for reference;
- Spam, junk mail and Listserv messages; and
- Blank forms.

Any records that are not required to be retained pursuant to this Guidance may be disposed of by the applicable PI or his/her department or laboratory. Note that any records created, retained or stored in information systems or on Endpoints (as defined in the Information Security Charter), should be disposed of in compliance with the University's **Sanitization and Disposal of Information Resources Policy.**

F. Access to Research Data

The University has the right of access to Research Data arising from all University Research, regardless of the location of the PI.

When necessary to ensure appropriate access, the University has the option of taking physical custody of the Research Data.

The University expects PIs to make Research Data available to other researchers both within and outside of the University who may wish to use such Data, as appropriate and in accordance with sponsor mandates with respect to public access to Research Data.

Other University investigators associated with a collaborative research project may have the need to review records of Research Data in the custody of the PI for the project. Research Data must be available to such investigators, when such access is appropriate. Research Data must be available to representatives of external sponsors of the research or designated governmental officials, when such access is appropriate.

G. Procedures in the Event that an Investigator Leaves the University

When an individual other than the PI who has been involved in a University Research project leaves the University, in general, he/she may take copies of Research Data for any project on which he/she worked, subject to agreement by the PI and any applicable sponsor restrictions. Original Research Data, however, must be retained at the University by the PI.

When a PI leaves the University, and a University Research project is to be moved to another institution, original Research Data may be transferred only with the approval of (1) the applicable school, department or center; (2) the PI's new institution, pursuant to a written agreement between the University and such institution that guarantees: (a) such institution's acceptance of custodial responsibilities for the Data and (b) the University's access to the Data as necessary; and (3) any sponsor that requires prior approval.

The University may refuse to permit the transfer of original Research Data for any reason it deems appropriate, may impose conditions on such transfer or may require the PI to leave copies of the Research Data with the University. In addition, other University investigators associated with a collaborative research project may make copies of Research Data prior to a permitted transfer by the PI, unless restricted by the specific terms of an applicable agreement with the sponsor of the research.

Any individual who leaves the University, whether to move to another institution or to retire, must make arrangements with his/her school, department or center for the storage of any Research Data that remains at the University in accordance with this Guidance and any policy adopted by the applicable school, department or center.

When the University permits a PI to leave the University with original Research Data, he/she must hold the Research Data in trust for the University. A departing PI must return the Research Data to the University if requested. In addition, such Research Data must be available to external sponsors, designated governmental officials and other University investigators who are collaborators with the departing PI.

Any disputes with respect to access to Research Data shall be resolved in the first instance by the applicable department chair or center director, and if not so resolved, by the EVPR or, with respect to research conducted at Columbia University Medical Center, the Senior Vice Dean for Research.

IV. Selected Regulations, Policies and Resources Applicable to Research Data Retention

Certain regulations, University policies and resources applicable to research data retention are listed in Appendix A hereto.

Selected Regulations, Policies and Resources Applicable to Research Data Retention

A. **Resources**

1. Research Data at Columbia University website:
   https://research.columbia.edu/research-data-columbia

2. Research and Data Integrity (ReaDI) Program
   http://www.columbia.edu/cu/compliance/docs/ReaDI_Program/index.html

3. Columbia University Libraries Research Data Services Program
   http://scholcomm.columbia.edu/data-management/

B. **Regulations**

1. 2 CFR 200.333: Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards: Retention Requirements for Records
   https://www.ecfr.gov/cgi-bin/text-idx?SID=60623b20e6213558b4aa6ab7eb76b619&node=2:1.1.2.2.1.4&rgn=div6#se2.1.200_1333

2. 45 CFR 46: Federal Policy for the Protection of Human Subjects (The Common Rule)
   http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title45/45cfr46_main_02.tpl

3. 21 CFR 56: FDA Regulations: Institutional Review Boards
   http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title21/21cfr56_main_02.tpl

4. 21 CFR 312.57 and 312.62: FDA Regulations: Retention of IND Records
   http://www.ecfr.gov/cgi-bin/text-idx?SID=a465b320ca228bef4cc6daa079a992f4&mc=true&node=pt21.5.312&rgn=div5#se21.5.312_157.
   http://www.ecfr.gov/cgi-bin/text-idx?SID=816b07aba287922c3416fe6abacf6248&mc=true&node=pt21.5.312&rgn=div5#se21.5.312_162

5. 21 CFR 812: FDA Regulations: Retention of IDE Records
   http://www.ecfr.gov/cgi-bin/text-idx?SID=816b07aba287922c3416fe6abacf6248&mc=true&tpl=/ecfrbrowse/Title21/21cfr812_main_02.tpl

6. 45 CFR.164: HIPAA Regulations on Retention of Protected Health Information
   http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title45/45cfr164_main_02.tpl

C. Policies

1. Columbia University Information Security Charter
   http://policylibrary.columbia.edu/information-security-charter

2. Columbia University Data Classification Policy
   http://policylibrary.colmbia.edu/data-classification-policy

3. Columbia University Sanitization and Disposal of Information Resources Policy
   http://policylibrary.columbia.edu/sanitization-and-disposal-information-resources-policy

4. Columbia University Records Retention Policy
   http://policylibrary.columbia.edu/columbia-university-records-retention-policy

5. Sponsored Projects Administration Records RetentionPolicy
   http://policylibrary.columbia.edu/sponsored-projects-administration-records-retention-policy

6. Columbia University Statement of Policy on Proprietary Rights in the Intellectual Products of Faculty Activity
   http://www.columbia.edu/cu/vpaa/handbook/appendixd.html

7. Columbia University Copyright Policy
   http://policylibrary.columbia.edu/copyright-policy

8. Columbia University Policy on Research Misconduct
   http://www.columbia.edu/cu/compliance/docs/research_misconduct/