

# Research Data: Recording, Retention & Access Procedures

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## Responsible College Officer

Executive Vice Dean for Research

## Responsible Office

Office of the Executive Vice Dean for Research

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## Procedure Statement

Research investigators and Weill Cornell Medical College share an obligation to appropriately record research data, archive it for a reasonable length of time, and make it available for review under appropriate circumstances.

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## Procedure Requirements

### Recording of Data

Researchers, Investigators and the College share an obligation to record research data appropriately and may be in raw, preliminary, or final. The term data includes technical data, digitally recorded data, laboratory worksheets, memoranda, notes or exact copies thereof that are the result of original observation and activities of a study and are necessary for reconstruction and evaluation of the report or publication of the study. In clinical investigations, this term also includes case history records and study protocol.

Principal Investigators/Senior Investigators are responsible to know and understand the data recording standards specific to the research or discipline; they are obliged to convey this information to the research team. Recognizing that certain information may be generated (for example, instrument test runs, set-up runs, etc.) which is not research data. The Principal Investigator/Senior Investigator shall make the final determination regarding what research data needs to be retained under this policy. Reliance should be placed on discipline-specific standards, expectations and the judgment of the senior members of the research team.

In the case of graduate students conducting research not integrated into the project of a research group directed by a Principal/Senior Investigator, the students special committee chair (Ithaca) or Major Sponsor (Weill Cornell) assumes the role and responsibilities of the Principal/Senior Investigator. In particular, the special committee chair or Major Sponsor bears primary responsibility for the overall conduct of research including data recording, management, and retention consistent with discipline-specific standards, discussing with the graduate student advisee, and assuming responsibility for access to data and provide access in accordance with this policy.

### Retention of Data

Research data generated by faculty, staff, students, and any others involved in the design, conduct or reporting of research at Weill Cornell Medical College, are to be retained by Weill Cornell Medical College for a minimum period of six years after submission of the final report on the research project and/or the publication of the research results for which the data were collected.

Longer periods of retention may be required in the following circumstances:

- if the sponsored agreement funding the research specifies a longer period of retention;
- data must be kept for as long as may be necessary to protect any intellectual property resulting from the work;
- if any charges regarding the research arise, such as allegations of scientific misconduct or conflict of interest, data must be retained until such charges are fully resolved; and
- if a student is involved, data must be retained until the degree is awarded or it is clear that the student has abandoned the work.
- Any research study data that involves Protected Health Information (PHI) or other pertinent information such as medical records, protocols, case history forms, clinical trial agreements as well as all progress reports and final reports must be retained for a minimum of 7 years after the date of the last patient visit or for minors or OB patients, the latter of 7 years from last patient visit or age 21. Whichever is longer.

The Principal Investigator/Senior Investigator shall assume primary responsibility for maintenance of the data during the retention period. Data will normally be maintained in the unit where they are produced. Data must be retained on the University campus, or in facilities under the auspices of the College, unless specific permission to do otherwise is granted by the Executive Vice Dean of Research. However, when the data are to be retained at a remote facility or location where they were originally generated (e.g., as part of a collaborative research program), the Principal Investigator/Senior Investigator should ensure that the data are retained and managed in accordance with this policy.

In recognition of the growing importance that data sharing and reuse of data (particularly digital data) play in the research process, Principal/Senior Investigators are encouraged to consult with Cornell University Library to explore possibilities for providing access to their research data, and ensuring its long-term retention.

#### Access to Data

The Principal Investigator/Senior Investigator shall assume responsibility for access to the data. Such data must be available to others within the College, representatives of external sponsors of the research, or designated governmental officials, when such access is appropriate. Where necessary to assure needed and appropriate access, the College has the option to take custody of the data in a manner specified by the Executive Vice Dean of Research.

When individuals involved in research projects at the College, including graduate students, leave the College, they may be provided copies of research data that they generated. The Principal Investigator/Senior Investigator, however, must retain research data at Weill Cornell Medical College.

If the Principal Investigator/Senior Investigator leaves Weill Cornell Medical College, and a project is to be moved to another institution, he/she must recognize that the College must have access to the data. Where it is feasible, a copy of the data shall be created to remain at the College. When creating a copy is not feasible and the research data is moved, departing investigators must understand that they have an obligation to hold these data in trust for the College and that such data must be returned to the College if requested during the six year period after submission of the final report or publication on the research project for which the data were collected, unless a longer retention period was specified by the sponsor. In circumstances that do not permit the orderly execution of the provisions of this policy (e.g., death of the Principal Investigator/Senior Investigator), the logical successor to the research project or the department chair, center or laboratory director, shall assume responsibility of the research data.

### Disputes

Disputes regarding requests for research data, copies of data, or transfer of data will be resolved by the Executive Vice Dean for Research or his designee.