Guidance - Retention of and Access to Research Data and Records

This guidance was established to assure that research data and records is appropriately recorded and archived for a reasonable period of time and available for review under the appropriate circumstances.

All research projects conducted by Geisinger researchers, physicians, staff, students and any other persons at Geisinger involved in the design, conduct or reporting of research at or under the auspices of Geisinger, must follow appropriate data retention policies.

Accurate and appropriate research data and records are an essential component of any research project. Both Geisinger and the PI have responsibilities and rights concerning access to, use of, and maintenance of original research data.

The principal investigator of an application approved by the IRB is required to retain records associated with a human subjects research project. The recordkeeping requirements vary depending on funding (e.g. federal, industry, private, etc.) with contractual provisions that would govern data retention, or whether the protocol was conducted under Food and Drug Administration (FDA) regulations.

Definition

Research data, as well as any other records that are necessary for the reconstruction and evaluation of reported results of research and the events and processes leading to those results, regardless of the form or the media on which they may be recorded. Geisinger investigators must retain research data in sufficient detail and for an adequate period of time to enable appropriate responses to questions about accuracy, authenticity, primacy, and compliance with laws and regulations governing the conduct of the research. It is the responsibility of the PI to determine what needs to be retained.

- **Data** means information collected as part of the research and any regulatory requirements.
- **Records** means all records or documents and communication which individually and collectively permit evaluation of the conduct of the research and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator and the sponsor.
- **HIPAA Authorization** means either (1) the copy of the signed Consent Forms or (2) the stand-alone authorization or (3) documentation of verbal authorization.
- **HIPAA Waiver** means the record of the IRB determination of a waiver of.

Ownership

Geisinger's ownership and stewardship of the data and records conducted at Geisinger, under the auspices of Geisinger, or obtained with Geisinger resources are based on both Federal regulation and sound management principles. Geisinger's responsibilities include but are not limited to:

- complying with the terms of any sponsored project agreements
- ensuring the appropriate use of human subjects, recombinant DNA, radioactive materials, etc.

Collection and Retention

The PI is responsible for the collection, management, and retention of research data and records. PIs should adopt an orderly system of data organization and should communicate the chosen system to all members of a research group and to the appropriate administrative personnel, where applicable. Particularly for long-term research projects, PIs should establish and maintain procedures for the protection of essential data and records in the event of a natural disaster or other emergency.

Federal Requirements

- Federal regulations for record retention and access to records for awards to recipients are set forth in OMB Circular A-110, (Uniform Administrative Requirements for Grants and Agreements and in various regulations including 45CFR74 and 45CFR92. This would include: financial records, supporting documents, statistical records, and all other records pertinent to an award to the grantee or subgrantees. The minimum retention period is 3 years but individual granting agencies can require longer periods of up to 7 years.
- For Investigational New Drug (IND) research, the FDA requires that sponsors and investigators retain "records and reports required by this part for 2 years after a marketing application is approved for the drug; or if an application is not approved for drug, until 2 years after shipment and delivery of the drug for investigational use is discontinued and the FDA so notified."
- For Investigational Device Exemption (IDE) research, the FDA requires the investigator or sponsor to maintain the records "for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated of completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol."

HIPAA:

If a Geisinger uses or discloses PHI based on an IRB approval of a waiver or an alteration of the Authorization requirement, the Principal Investigator (PI) must retain the IRB's documentation on which it relied for at least 6 years from the date the waiver or alteration was obtained, or the date when it was last in effect, whichever is later.

Geisinger requires investigators to retain study records, along with records of all disclosures of study information, for the following time periods:

1) At least six years after the last subject has completed his or her participation in the study, or
2) The date of the last disclosure of identifiable health information from study records, if disclosures continue after all subjects have completed the study. 45 CFR 164.528

This requirement to retain study records and to account for disclosures also applies to research that involves the secondary use of medical records or other identifiable health information.

Where research is funded by a contract that includes specific provision(s) regarding ownership, retention of and access to technical data, the provision(s) of that agreement will guide the data retention requirements for the project.

Except where precluded by the specific terms of sponsorship or other agreements, tangible research property, including the scientific data and other records of research conducted under the auspices of Geisinger, belongs to Geisinger. The PI is responsible for the maintenance and retention of research data.

Study Data and Record Retention Requirements	
	Minimum Retention Period
Records	3 years after study completion
Federally Funded Research	3 years after expiration of grant period
HIPAA Authorization (often combined with research consent)	6 years after completion of study
HIPAA Waiver or Alteration	6 years after completion of study
FDA (Industry sponsored or other contractual studies which would include industry, private, foundation, etc.)	2 years after last marketing approval

Beyond the period of retention specified here, the destruction of the research record is at the discretion of the PI and his or her department.

Records will normally be retained where they are produced. Research records must be retained in facilities under the auspices of Geisinger, unless specific permission to do otherwise is granted by the Chief Scientific Officer or his/her designee.

Access

Where necessary to assure needed and appropriate access, Geisinger has the option to take custody of the data in a manner specified by the Chief Scientific Officer or his/her designee.

Transfer in the Event a Researcher Leaves Geisinger

If a PI leaves Geisinger, and a project is to be moved to another institution, ownership of the data may be transferred with the approval of the Chief Scientific Officer or his/her designee, and with written agreement from the PI's new institution that guarantees: 1) its acceptance of custodial responsibilities for the data, and 2) Geisinger access to the data, should that become necessary.