

SWOG Record Retention Guidance

Objective

Due to space limitations, institutions frequently seek guidance on record retention requirements for research records. This policy provides a mechanism for notifying institutions when it is acceptable to destroy research records including IRB records, investigational drug records, and patient records.

Background

The Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) have regulations related to retention of research records.

The DHHS regulation (45 CFR 46.115) applies to all research conducted or supported by a Federal department or agency. This regulation states that IRB records relating to research conducted shall be retained for at least 3 years after completion of the research. The FDA regulation (21 CFR 56.115) also states that IRB records must be retained for at least 3 years after completion of the research.

Clinical investigations that utilize an Investigational New Drug (IND) must additionally comply with 21 CFR 312.62. This regulation applies to investigational drug records and patient case histories. The regulation requires that the investigator retain records for 2 years after a marketing application is approved for the drug for which it is being investigated. If no application is filed or if the application is not approved, records are retained until 2 years after the investigation is discontinued and the FDA is notified.

Procedures

The report “List of Protocols with No Required Follow-up” that is available on the CRA Workbench of the SWOG website provides the date when all requirements outlined above have been met group wide. After that date, records may be destroyed according to HIPAA requirements. If an institution never enrolled a patient on a study, IRB records may be destroyed three years after the study is closed out locally. Note that these are minimal requirements for record retention and more stringent local institutional policies must be adhered to, if applicable.

For questions, contact the SWOG Quality Assurance Department at qmail@swog.org