

SWOG FAQs

We are running out of room and are wondering how long we need to keep patient charts and protocols for closed studies.

The Record Retention Guidance document describes when it is acceptable to destroy research records including IRB records, investigational drug records, and patient records. The report "List of Protocols with No Required Follow-up" available on the CRA Workbench provides a mechanism for informing institutions of the specific record retention requirement for each of our studies.

During the interim until records may be destroyed, records may be scanned and stored electronically as long as they can be easily retrieved in the case of an audit or FDA inspection.

Why are there studies on the List of Protocols with No Required Follow-up that have been closed for years and still do not have a destruction date posted in this report?

Most of these are studies for which either CTEP or SWOG holds the Investigational New Drug (IND) permit. Multiple studies may be added over time to an IND so it can remain active for years, until follow-up for *all* of these studies has ended. Other studies without a destruction date are intergroup studies, and we cannot post a date until the coordinating group provides us with this information.

When a study closes to accrual, can we close it out with our IRB if we never enrolled any patients? What about studies with registered patients who all have died or completed their protocol specified follow up period?

It is acceptable to close out any studies that never had accrual. For studies with registered patients who are no longer being followed, you may close the study out with the IRB when it gets added to the List of Protocols with No Required Follow-up. This list is available on the CRA Workbench and provides a list of studies whose follow-up and data collection have been completed group wide. Until the final analysis is complete, the statisticians may require additional data collection or clarification of previously submitted data and this ensures that the study remains open at all sites for data submission.

Does SWOG require IRBs to review external safety reports and internal Serious Adverse Events?

SWOG has no policy on review of safety reports. We defer to the policies and procedures of the local IRB although we encourage institutions to follow the guidance provided by the FDA and OHRP in regard to reporting of external adverse events. These guidance documents were issued in response to concerns raised by the IRB community that increasingly large volumes of individual adverse event reports submitted to IRBs — often lacking in context and detail — are inhibiting, rather than enhancing, the ability of IRBs to protect human subjects. The OHRP guidance clarifies that only a small subset of adverse events occurring in human subjects participating in research are unanticipated problems that must be reported.

Can a Nurse Practitioner or other non-physician conduct physical exams or other duties required by protocol?

The registering investigator accepts full responsibility for the treatment and evaluations of patients on research protocols; however, the investigator may delegate some of these duties to a qualified health

professional (e.g., nurse practitioner) provided these duties fall within the scope of practice allowed for that locale. A “qualified health professional” is any individual involved in the conduct of the study that is performing functions within the scope of their professional license.

It is recommended that any individual who makes clinical decisions regarding study subjects be listed as a sub-investigator on the 1572. The duties delegated to these individuals must also be documented on the SWOG Site Authority Log or Delegation of Task Log which must be available for review at the time of an audit.

Do I need to report protocol deviations to SWOG?

Protocol deviations should be reported to your IRB of record according to the IRB’s policies and procedures. Only those deviations that indicate research participants may be at greater risk of harm (physical or otherwise) than previously anticipated should be reported to SWOG. Deviations including a corrective and preventive action plan should be reported to the Quality Assurance Manager at (210) 614-8808 or qamail@swog.org.

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