

Is this "document" a Clinical Research Record (CRR)?

See DAIDS Policy "Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials" and its appendix "Essential Documents Recordkeeping Requirements"

YES

Is this CRR part of a US FDA IND Study?

YES

Retain CRR for 2 years after the FDA Approval or Disapproval, IND Withdrawal, or Study Discontinuation as per US FDA 21 CFR 312.62(c)

NO

Retain CRR for at least 3 years after completion of research as per HHS 45 CFR 46.115(b) *

NO

Is this "document" subject to any US Federal or State, country or local laws, regulations, policies, or other requirements?

YES

Follow the strictest of any applicable laws, regulations, policies, or other requirements for record retention

NO

Retain "document" as per institution's own policies and procedures, IF ANY

Is this CRR also subject to any other US Federal or State, country or local laws, regulations, policies or other requirements?

Follow the strictest of any applicable laws, regulations, policies or other requirements for record retention of CRR

* See DAIDS Policy on "Storage and Retention of Clinical Research Records" for definition of completion of research for DAIDS clinical research studies.