

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.

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) *

AND

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

NO

AND

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

NO

YES

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

NO

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

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

YES

* See DAIDS Policy on "Storage and Retention of Clinical Research Records" for definition of completion of research for DAIDS clinical research studies at <http://www3.niaid.nih.gov/research/resources/TO BE DETERMINED/Regulatory.htm>