CRR must be retained in compliance with International Council for Harmonization (ICH) E6 (4.9.5)

Is this CRR part of a United States (U.S.) FDA Investigational New Drug (IND) Study?

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

No: Retain CRR for at least 3 years after completion of research as per HHS 45 CFR Part 46.115 (b)

And

Is this CRR also subject to any other US Federal or State, Local Regulations, policies and other requirements?

No: Follow the strictest of any applicable regulations, policies, or other requirements for record retention.

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