Is this “document” a Clinical Research Record (CRR)?

- Yes: Retain CRR for at least 3 years after completion of research as per HHS 45 CFR Part 46.115 (b)
- No: These record retention requirements do not apply. Retain “document” as per institution’s policies and procedures, IF ANY, AND Follow the strictest of any applicable requirements for record retention (such as local, institutional, etc.)

Is this CRR also part of a clinical trial?

- Yes: CRR must also be retained in compliance with International Council for Harmonization (ICH) E6 (4.9.5)
- No: Retain CRR for at least 3 years after completion of research as per HHS 45 CFR Part 46.115 (b) AND Follow the strictest of any applicable requirements for record retention (such as local, institutional, etc.)

Is this clinical trial also under a United States (U.S.) FDA Investigational New Drug (IND) Application?

- Yes: Also, 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 as per 45 CFR Part 46.115 (b) AND ICH E6 (4.9.5) AND Strictest of any Other applicable requirements (including other non-US regulatory authorities like SAPHRA, EMA, etc. as well as such as institutional, local, etc.)