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.

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)
  - AND
    - Is this CRR also subject to any other US Federal or State, country or local laws, regulations, polices, or other requirements?
      - NO
      - Follow the strictest of any applicable laws, regulations, policies, or other requirements for record retention
      - YES
      - Follow the strictest of any applicable laws, regulations, policies, or other requirements for record retention of CRR

- NO
  - Retain CRR for at least 3 years after completion of research as per HHS 45 CFR §46.115(b) *
  - AND
    - Is this "document" subject to any US Federal or State, country or local laws, regulations, polices, 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 polices and procedures, IF ANY

* 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