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| **Does the regulatory binder have included:** | |
| Yes | CVs for all research team members, signed and dated within the last 2 years |
| Yes | GCP Training for all research team members and is within expiration |
| Yes | Medical License for all PIs, Sub-Is, Research Nurse, or Pharmacist |
| Yes | Signed Conflict of Interest (COI) forms from the PI and all Sub-Is |
| Yes    N/A | Signed Financial Disclosure Forms (FDF) from the PI and all Sub-Is |
| Yes | Study Protocol (and any amendments). If applicable, signed Protocol Signature Page(s) (PSP) |
| Yes  N/A | Investigator Brochure (and any amendments). If applicable, signed IB Signature Page(s) |
| Yes | Informed Consent Template for any IRB approved version |
| Yes | Any IRB submissions and approval letters |
| Yes  N/A | Monitor Confirmation and Follow-up Letters |
| Yes | Training Log |
| Yes  N/A | Any other study logs |