|  |
| --- |
| **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 |