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| <ul style="list-style-type: none"> <li>Key Study Materials</li> <li> <ul style="list-style-type: none"> <li>Protocol - ICF - IB</li> <li>Manuals &amp; Procedures</li> </ul> </li> </ul> | <p>Clinical Study Report, Site Contact Details, Sponsor/CRO Contact Information</p> <p>Informed Consent Form (blank), Investigator Brochure, Marketed Product Material, Protocol, Protocol Clarification, Protocol Summary of Changes</p> <p>Decoding Procedures, Procedure Manual, Sample Case Report Form</p> |
| <ul style="list-style-type: none"> <li>Participant Facing</li> <li> <ul style="list-style-type: none"> <li>Recruiting &amp; Consenting</li> <li>Study Conduct</li> </ul> </li> </ul>     | <p>Advertisement for Recruitment, Informed Consent Form (blank)*, Participant Information Sheet</p> <p>Diary (blank), Participant Materials - Other, Participant Questionnaire (blank), Study Participation Card</p>  |
| <ul style="list-style-type: none"> <li>Participants</li> <li> <ul style="list-style-type: none"> <li>Logs</li> <li>Source</li> <li>CRFs</li> </ul> </li> </ul>                           | <p>Participant Adverse Event Log, Participant Enrollment Log, Participant ID Code List, Participant Screening Log, Protocol Deviations, Specimen Tracking</p> <p>Informed Consent Form (signed), Source</p> <p>Completed CRFs</p>   |
| <ul style="list-style-type: none"> <li>IRB/IEC</li> <li> <ul style="list-style-type: none"> <li>Submissions</li> <li>Compliance &amp; Qualifications</li> </ul> </li> </ul>              | <p>IRB/IEC Response, IRB/IEC Submission</p> <p>IRB/IEC Compliance, IRB/IEC Composition, Reliance Agreement</p>  |
| <ul style="list-style-type: none"> <li>Reg Authority Submissions</li> </ul>  | <p>Regulatory Authority Response, Regulatory Authority Submission</p>   |
| <ul style="list-style-type: none"> <li>Other Committees</li> </ul>   | <p>Ancillary Committee Response, Ancillary Committee Submission</p>   |
| <ul style="list-style-type: none"> <li>Monitoring</li> </ul>   | <p>Monitoring Visit Confirmation Letter, Monitoring Visit Follow Up Letter, Monitoring Visit Log</p>  |
| <ul style="list-style-type: none"> <li>PI Oversight</li> </ul>   | <p>1572 or Equivalent, Acceptance of IB, Acceptance of Marketed Product Materials, Delegation of Authority, Protocol Signature Page</p>   |
| <ul style="list-style-type: none"> <li>Staff</li> <li> <ul style="list-style-type: none"> <li>Qualifications</li> <li>Financial Disclosures</li> </ul> </li> </ul>                       | <p>Biosketch, CV, Medical License, Signature &amp; Initials, Training Evidence (non study-specific)</p> <p>Conflict of Interest, Financial Disclosure Form</p>  |
| <ul style="list-style-type: none"> <li>Study Training</li> </ul>   | <p>Training Evidence (study-specific), Training Material</p>  |
| <ul style="list-style-type: none"> <li>Safety</li> </ul>   | <p>Adverse Event Report, Expedited Safety Report</p>  |
| <ul style="list-style-type: none"> <li>IP &amp; Supplies</li> </ul>  | <p>Equipment Log, Investigator Brochure*, IP &amp; Supply Shipping, IP Accountability, IP Destruction, IP Excursions, IP Instructions for Handling, IP Sample Label, Marketed Product Material*</p>   |
| <ul style="list-style-type: none"> <li>Lab</li> </ul>  | <p>Lab Certification, Lab Director Qualifications, Lab Normal Ranges</p>  |
| <ul style="list-style-type: none"> <li>Correspondence &amp; Notes to File</li> </ul>   | <p>Correspondence, Note to File, Site Activation</p>  |
| <ul style="list-style-type: none"> <li>Contracts &amp; Budgets</li> </ul>  | <p>Budget, Confidentiality Agreement, Contract, Data Privacy Form, Insurance, Internal Budget, Invoice</p>  |
| <ul style="list-style-type: none"> <li>Feasibility</li> </ul>  | <p>Feasibility Questionnaire, Protocol Synopsis</p>   |

\* = secondary filing location for this record