Below is a list of common study documents, although it may not be all-inclusive. Please note that every protocol can differ in applicable requirements, complexity and needs, so there may be additional documents not listed. Similarly, some of the documents listed below may not apply or be useful to every study. Check those documents that apply to your study, and note the location of the document if stored in another location (e.g. electronic file).

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| **IRB Documentation** | | **Location** |
|  | IRB Submission and Review Tracking Log |  |
|  | New Protocols   * Complete application * IRB formal action letters (conditional approvals, deferrals) corresponding PI responses and pertinent correspondence * Final approval letter * Final consent/assent form(s) |  |
|  | Continuing Reviews   * Complete application * IRB formal action letters (conditional approvals, deferrals), corresponding PI responses and pertinent correspondence * Final approval letter * Final consent/assent form(s) |  |
|  | Amendments   * Complete application * IRB formal action letters (conditional approvals, deferrals), corresponding PI responses and pertinent correspondence * Final approval letter * Final consent/assent form(s) |  |
|  | Unanticipated Problems/Event Reports (including Significant Deviations)   * Complete Report * IRB response, corresponding PI Response and pertinent correspondence * Final IRB Acknowledgment letter (& amended materials if applicable) |  |
|  | Unanticipated Problems/Events Tracking Log |  |
|  | Minor Deviation Reports and Exception Requests   * Complete Report * IRB response, corresponding PI Response and pertinent correspondence * Final IRB Acknowledgment letter (& amended materials if applicable) |  |
|  | Minor Deviation and Exceptions Tracking Log |  |

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| **Study Staff Logs and CVs** (documentation of qualifications/training) | | **Location** |
|  | Roles & Responsibilities Log |  |
|  | Staff Signature Log |  |
|  | Research Staff CVs and Qualifications |  |
|  | Training Documentation Log |  |

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| **Study Protocol** | | **Location** |
|  | Current, approved Study Protocol |  |
|  | Expired Study Protocol versions versions: |  |

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| **Informed Consent and Assent Forms** | | **Location** |
|  | Current, approved Informed Consent/ Assent Forms (stamped copy) |  |
|  | Expired Informed Consent and Assent Forms version(s): |  |
|  | Consent Revision Log |  |

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| **Standard Operating Procedures** | | **Location** |
|  | Standard Operating Procedures (SOPs) |  |
|  | SOPs version(s): |  |

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| **Recruitment Materials** | | **Location** |
|  | Recruitment Materials (posters, letters, mailings, thank you’s, etc.) |  |
|  | Expired recruitment materials version(s): |  |
|  | Recruitment Log |  |

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| **Reports: Data Safety Monitoring** | | **Location** |
|  | Data Safety Monitoring Plan (and committee) |  |
|  | Data Safety Monitoring Reports & Meeting Minutes/Correspondence |  |

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| **Reports: External Monitoring** | | **Location** |
|  | Monitoring Log (documentation of external sponsor/regulatory audit) |  |
|  | Monitoring/Audit Reports and/or Letters |  |

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| **Subject Tracking Documents: Screening & Enrollment** | | **Location** |
|  | Subject Screening Log |  |
|  | Subject Enrollment Log |  |
|  | Subject Identification code list (Key) |  |

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| **Subject Case Histories** | | **Location** |
|  | Signed informed consent/assent forms |  |
|  | Signed, dated and completed case report forms |  |
|  | Documentation of CRF corrections |  |
|  | Source documents |  |

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| **Case Report Forms and Study/Subject Documents** | | **Location** |
|  | Current Case Report Forms (CRFs) (blank) |  |
|  | expired CRFs |  |
|  | List of Source Documents |  |
|  | Study and Subject Documents (blank copy of data collection tools, etc.) |  |

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| **Laboratory Documentation** | | **Location** |
|  | Normal Value/Range(s) |  |
|  | Certification/Accreditation for Facilities |  |
|  | Lab Director’s CV |  |
|  | CLIA Certification |  |
|  | Certification of Analysis |  |

For Investigational Drug and Device studies:

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| **Regulatory Documentation** (drug/device studies) | | **Location** |
|  | FDA Form 1572 (all versions) Drug, PI |  |
|  | FDA Form 1571 (all versions) Drug, Sponsor |  |
|  | IDE Statement of Investigator’s Commitment Device, Sponsor-PI |  |
|  | FDA Annual Reports |  |
|  | FDA Financial Disclosure Form(s) |  |
|  | Drug/Device Accountability Log Research Pharmacy   * Shipping records * Randomization Codes |  |
|  | Sample Label for Investigational Product |  |
|  | IRB Membership Roster |  |

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| **Investigational Brochure** | | **Location** |
|  | Current Investigational Brochures |  |
|  | Expired Investigational Brochures |  |
|  | Investigational Brochure updates |  |

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| **Investigator Agreement/Contract** | | **Location** |
|  | Investigator Agreement |  |
|  | Confidentiality agreement b/w investigator & sponsor |  |
|  | Insurance or indemnification letter |  |

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| **Grant Application, Reporting & Correspondence** | | **Location** |
|  | Grant Application |  |
|  | Sponsor Progress Reports |  |
|  | Relevant Correspondence |  |

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| **Other** | | **Location** |
|  | Equipment and Supplies (receipt, calibration and maintenance logs) |  |
|  | Financial agreements (budget contracts) |  |
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