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| ***Main Tabs*** | ***Sublevel 1*** | Sublevel 2 |
| ***IRB Submissions/Approved Documents*** | ***Study Research Plan/Protocol*** | The most updated, currently approved version of the research plan. |
|  |  | All superceded versions of the research plan. |
| ***Informed Consent & Assent Forms*** | The most updated, currently approved versions of consent/assent forms |
|  | All expired/superceded versions of the consent/assent forms. |
| Consent Revision log (**optional, but recommended**) – tracking changes to consent/assent forms, the date submitted for IRB review, and date approved by the IRB. |
| ***Recruitment Materials*** | All currently IRB approved recruitment materials |
|  | All superceded versions of recruitment materials. |
| Recruitment Revision Log (**optional**) tracking changes to materials, data submitted to the IRB, and date approved by the IRB |
| ***Instruments*** | All current IRB approved instruments |
|  | All superceded versions of instruments. |
| Recruitment Revision Log (**optional**) tracking changes to instruments, data submitted to the IRB, and date approved by the IRB |
|  | ***Adverse Events & Unanticipated Problems (Problem Event Reports)*** | Reports to the IRB and correspondence regarding event and report |
|  |  | Final IRB acknowledgment Letter |
| Adverse Event and Unanticipated Problem Log (**optional**) |
| ***Protocol Deviations*** | Documents showing dates and reasons for any deviation from the protocol. We suggest you keep Protocol deviation log as a way to keep track of deviations before they are reported with the annual progress report. |
| ***IRB Documentation*** | Complete applications and documentation for initial review, continuing reviews, and amendments, problem event reports, final study report |
|  | All official correspondence with the IRB, including email communications with responses to IRB inquiries and concerns. |
| Local IRB approvals, research site permissions |
| IRB Tracking Log (**optional**) – Tracks submissions, IRB actions, PI responses and correspondence |
| ***DSMB Reports or Summaries*** | Copies of all reports and summaries. |
|  | Description of DSMB Charter, if not in protocol or research plan |
| List of Data Safety Monitoring Board Members and affiliations |
| ***Case Report Forms*** | Current and complete set of blank case report forms (CRFs) |
|  | Out of date case report forms (CRFs) |
| Source document list |
| ***Protocol Operations*** | ***Subject Screening and Enrollment*** | Completed screening logs |
|  |  | Subject enrollment log |
| ***Standard Operating Procedures*** | Current version of the SOPs. |
|  | All superceded versions of the SOPs. |
| ***Notes-To-File*** | A note or memo that documents and explains any discrepancies, clarifies any questionable data, or study procedures. |
|  | A note or memo that documents where certain documents are stored in places other than the regulatory binder (i.e. a note to file indicating that signed case report forms are kept in study subjects files, etc.). |
| **S*tudy/Subject Documents*** | Blank copy of surveys and questionnaires |
|  | Subject Inclusion/Exclusion checklist |
| Study visit checklist |
| ***Study Staff Information*** | Roles & Responsibilities Log |
|  | Staff Signature Log (can be included with the roles and responsibilities log) |
| CVs, licenses (if applicable) |
| Training Certifications (Human Subjects Research, GCP, HIPAA, etc.) |
| ***Sponsor (e.g. NIH, USAID, BMGF, etc.)*** |  | Copy of the approved sponsor grant application or contract. |
|  |  | All Progress Reports submitted to sponsor. |
| All forms submitted to sponsor pertaining to human subjects research. |
| All correspondence with sponsor (the retained communications includes all required reports, e-mails, faxes, memoranda, and letters. In addition, we encourage logging phone conversations to record when conversations take place, and generating minutes to document the substance of these communications.) Include email verification when enrollment begins. |
| ***Regulatory Oversight (FDA, CLIA, etc.)*** | ***FDA Form 1572 & 1571*** | Copies of all versions of FDA Form 1572 (Statement of Investigator) for all involved investigators (documents must be updated with the study sponsor each time there is a change to the information originally provided. Copies of all versions should be maintained.  Copy of the Investigational New Drug Application (FDA Form 1571), if the PI is also the sponsor; and, all versions of the FDA Form 1571 submitted with amendments to the FDA. |
|  | ***IND/IDE Annual Reports to the FDA for Investigator-Sponsored Studies*** | All annual reports filed with the FDA. |
| ***Monitoring Log/Report*** | Optional - All Monitoring Reports (required for all FDA studies) |
|  | Monitoring Log (required for all FDA studies) – documents all monitoring visits and reviews (e.g. site visits, FDA audits). |
| ***Drug/Device Accountability Log*** | A record to document the shipment, receipt, use of and disposal of all investigational drugs/devices used for the study. (This information may be stored in the pharmacy binder.) |
| ***Laboratory Documentation*** | Normal Value Range(s) for medical, laboratory, technical procedures and/or tests included in the protocol |
|  | Certification/Accreditation for all medical, laboratory, technical procedures and/or test included in the protocol |
| Lab Director’s Curriculum Vitae (CV) – CV should be current within 2 years. |
| Biosafety Registration information |
| CLIA (Clinical Laboratory Improvement Amendments) Certification |
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| Certification of Analysis – document which lists the tests, methods, specifications, and results of the in-process, bulk, and final lot release tests for each bulk and/or lot of drug, chemical, or vaccine manufactures. |
|  | ***Product Information*** | Investigator brochure and updates, and documentation of submission to the IRB. |
|  |  | Package insert |
| Device manual |
| Sample of product label |
| Instructions for handling investigational product(s) |