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| Investigators may use this checklist to conduct a self-audit or to prepare for a monitoring visit, compliance review, or audit. | | | |
|  | | | |
| IRB STU # | | |  |
| Protocol Title | | |  |
| Principal Investigator | | |  |
| Department | | |  |
| Sponsor | | |  |
| Velos # | | |  |
| List of All Performance Sites | | |  |
| Person Completing Checklist | | |  |
| Date Checklist Completed | | |  |
|  | | | |
| Yes  No  N/A | PI is acting as sponsor-investigator | | |
| Yes  No  N/A | Drug/biologic is under an IND. If yes, IND#: | | |
| Yes  No  N/A | If under IND, a current signed FDA 1571 (PI name should match the 1571 and the protocol) | | |
| Yes  No  N/A | If under IND, previous signed versions of FDA 1571 | | |
| Yes  No  N/A | A current signed FDA 1572 (PI name should match the 1572 and the protocol) | | |
| Yes  No  N/A | Previous signed versions of FDA 1572 | | |
| Yes  No  N/A | A current signed financial disclosure for each investigator listed on the 1572 | | |
| Yes  No  N/A | Previous versions of signed financial disclosures for each investigator listed on the 1572 | | |
| Yes  No  N/A | Valid licensure for each investigator listed on the 1572 | | |
| Yes  No  N/A | | Current investigator’s brochure and/or package insert | |
| Yes  No  N/A | | Previous versions of or updates to the investigator’s brochure and/or package insert | |
| Yes  No  N/A | Pharmacist maintains study drug inventory, drug accountability, and dispensing of study drug | | |
| Yes  No  N/A | Decoding procedures for blinded trials | | |
| Yes  No  N/A | Sample of labels attached to investigational product containers | | |
| Yes  No  N/A | Instructions for handling of investigational product(s) (if not in protocol or investigator’s brochure) | | |
| Yes  No  N/A | Shipping log for each drug under investigation, which captures the following: | | |
| Yes  No  N/A | Date shipment received | | |
| Yes  No  N/A | Shipment # from packing slip | | |
| Yes  No  N/A | Batch#/lot #/code mark | | |
| Yes  No  N/A | Expiration date | | |
| Yes  No  N/A | # of boxes, kits, or drugs per lot # | | |
| Yes  No  N/A | # of pills, vials, inhalers, or drugs per box or kit | | |
| Yes  No  N/A | Condition of study drug shipment (intact/damaged) | | |
| Yes  No  N/A | Receiver’s name | | |
| Yes  No  N/A | Accountability log for each drug under investigation, which captures the following: (may be kept in research pharmacy to protect the blind, if applicable) | | |
| Yes  No  N/A | If drug accountability records are kept elsewhere (e.g., in research pharmacy), a memo to indicate this is on file in the regulatory binder | | |
| Yes  No  N/A | Participant ID # | | |
| Yes  No  N/A | Lot or kit # | | |
| Yes  No  N/A | # of bottles, vials, etc. | | |
| Yes  No  N/A | Amount of study drug per bottle, vial, etc. | | |
| Yes  No  N/A | Total amount dispensed | | |
| Yes  No  N/A | Date dispensed | | |
| Yes  No  N/A | Initials of person dispensing | | |
| Yes  No  N/A | # of pills, bottles, vials, etc. returned | | |
| Yes  No  N/A | Date returned | | |
| Yes  No  N/A | Initials of person receiving the returned drug | | |
| Yes  No  N/A | Study drug reconciled (amount dispensed with amount that should have been taken with amount returned) | | |
| Yes  No  N/A | Comments: participant lost, discarded, etc. | | |
| Yes  No  N/A | Product storage requirements maintained (temperature, expiration dates checked, etc.) | | |
| Yes  No  N/A | If applicable, date and quantity of product returned to pharmacy | | |
| Yes  No  N/A | If authorized by sponsor/protocol, date and quantity of product destroyed | | |
| Yes  No  N/A | If authorized by sponsor/protocol, date and quantity of product returned to sponsor | | |
| Yes  No  N/A | Laboratory documentation: | | |
| Yes  No  N/A | Lab Director’s CV for each lab used is current and on file | | |
| Yes  No  N/A | CLIA cert. for each lab used is on file | | |
| Yes  No  N/A | CAP cert. for each lab used is on file | | |
| Yes  No  N/A | Current normal-range values for each reference lab is on file | | |
| Yes  No  N/A | Previous normal-range values for each reference lab is on file | | |
| Yes  No  N/A | Specimen tracking log is on file | | |
| Yes  No  N/A | Record of retained body fluids/tissue samples is on file | | |
| Yes  No  N/A | Oversight Committee (DSMB, DMC, Safety Officer, etc.): | | |
| Yes  No  N/A | Plan(s) (if not included as part of the study protocol) | | |
| Yes  No  N/A | Progress reports/reviews/recommendations | | |
| Yes  No  N/A | Meeting minutes | | |
| Yes  No  N/A | Correspondence | | |
| Yes  No  N/A | **Frequency of meetings**: | | |
| Yes  No  N/A | Oversight committee reports. **Number**: | | |
| Yes  No  N/A | Copies of all reports present in file. **Number**: | | |
| Yes  No  N/A | Correspondence with the IRB, including any required reports, is on file | | |
| Yes  No  N/A | Correspondence with the sponsor or monitor, including any required logs/reports, is on file | | |
| Yes  No  N/A | Correspondence with the FDA, including any required reports and IND authorization/approval, IND safety reports, etc., is on file | | |
| Yes  No  N/A | Investigator maintains proper control of the drugs under investigation | | |
| Yes  No  N/A | Investigator administers the drug only to participants under his/her supervision | | |
| Yes  No  N/A | Investigator does not supply the investigational drug to any person not authorized to receive it | | |
| Yes  No  N/A | If the investigation or the investigator’s part of an investigation is terminated, suspended, discontinued, or completed, investigator returns or otherwise disposes of any unused drug as directed or authorized by the sponsor | | |
| Yes  No  N/A | If an investigational drug is part of the Controlled Substances Act, investigators take adequate precautions, including storage of the investigational drug in a securely locked, substantially constructed cabinet or enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution | | |
| Yes  No  N/A | Investigator reports unanticipated problems involving risks to subjects or others (UPIRSOs) promptly to the IRB via the eIRB reportable event (RE) form according to HRPP’s Reportable Event policy | | |
| Yes  No  N/A | Investigator reports protocol violations (possible noncompliance) promptly to the IRB via the eIRB reportable event (RE) form according to HRPP’s Reportable Event policy | | |
| Yes  No  N/A | Investigator reports protocol changes without prior IRB approval which were necessary to avoid immediate apparent harm to participants promptly to the IRB via the eIRB reportable event (RE) form according to HRPP’s Reportable Event policy | | |
| Yes  No  N/A | Investigator reports major complaints promptly to the IRB via the eIRB reportable event (RE) form according to HRPP’s Reportable Event policy | | |
| Yes  No  N/A | Progress reports: The investigator submits progress reports on the investigation to the sponsor and reviewing IRB at regular intervals and at least yearly. | | |
| Yes  No  N/A | Progress reports to the IRB include: DSMB/DMC reports; IND safety reports; anticipated events or other problems; external, internal, or routine audit and monitoring reports; protocol deviations; minor complaints; or other relevant reports applicable to the conduct of the study | | |
| Yes  No  N/A | Investigator notifies reviewing IRB of study closure upon study termination or completion of the investigation. | | |
| Yes  No  N/A | Final Report: The investigator submits a final report to the sponsor and reviewing IRB within 3 months after termination or completion of the investigation. | | |

For questions, please contact the HRPP Office at [HRPP@utsouthwestern.edu](mailto:HRPP@utsouthwestern.edu) or 214-648-3060.