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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 or 214-648-3060.