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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 | Device is under an IDE. If yes, IDE#: |
| [ ]  Yes [ ]  No [ ]  N/A | Current signed Investigator Statement (PI name should match the Investigator Statement and the protocol) |
| [ ]  Yes [ ]  No [ ]  N/A | Previous signed versions of Investigator Statements |
| [ ]  Yes [ ]  No [ ]  N/A | Current signed financial disclosure for each investigator  |
| [ ]  Yes [ ]  No [ ]  N/A | Previous versions of signed financial disclosures for each investigator  |
| [ ]  Yes [ ]  No [ ]  N/A | Valid licensure for each investigator  |
| [ ]  Yes [ ]  No [ ]  N/A | Current device manual  |
| [ ]  Yes [ ]  No [ ]  N/A | Previous versions of or updates to the device manual |
| [ ]  Yes [ ]  No [ ]  N/A | If device is classified as non-significant risk (NSR), NSR determination was made by: [ ]  FDA [ ]  IRB |
| [ ]  Yes [ ]  No [ ]  N/A | If FDA-approved device is being used, current 510(k)  |
| [ ]  Yes [ ]  No [ ]  N/A | If HUD is being used, current HUD brochure |
| [ ]  Yes [ ]  No [ ]  N/A | Decoding procedures for blinded trials |
| [ ]  Yes [ ]  No [ ]  N/A | Sample device label  |
| [ ]  Yes [ ]  No [ ]  N/A | Instructions for handling device (if not in protocol or device manual) |
| [ ]  Yes [ ]  No [ ]  N/A | Shipping log for each device 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 # |
| [ ]  Yes [ ]  No [ ]  N/A | Expiration date |
| [ ]  Yes [ ]  No [ ]  N/A | # of boxes, kits, or devices per lot # |
| [ ]  Yes [ ]  No [ ]  N/A | # of devices per box or kit |
| [ ]  Yes [ ]  No [ ]  N/A | Condition of study device shipment (intact/damaged) |
| [ ]  Yes [ ]  No [ ]  N/A | Receiver’s name |
| [ ]  Yes [ ]  No [ ]  N/A | Accountability log for each device under investigation, which captures the following: |
| [ ]  Yes [ ]  No [ ]  N/A | Participant ID # |
| [ ]  Yes [ ]  No [ ]  N/A | Model or serial #  |
| [ ]  Yes [ ]  No [ ]  N/A | Date device dispensed/administered/used/implemented |
| [ ]  Yes [ ]  No [ ]  N/A | Initials of person dispensing/administering/implementing |
| [ ]  Yes [ ]  No [ ]  N/A | Date device returned |
| [ ]  Yes [ ]  No [ ]  N/A | Initials of person receiving the returned device |
| [ ]  Yes [ ]  No [ ]  N/A | Device reconciliation performed (if applicable) |
| [ ]  Yes [ ]  No [ ]  N/A | Comments, such as malfunctions, device failure, disposition of unused devices (returned to sponsor/destroyed) or any other pertinent information concerning the device |
| [ ]  Yes [ ]  No [ ]  N/A | Device storage requirements maintained (temperature, expiration dates checked, etc.) |
| [ ]  Yes [ ]  No [ ]  N/A | If authorized by sponsor/protocol, date and quantity of devices destroyed |
| [ ]  Yes [ ]  No [ ]  N/A | If authorized by sponsor/protocol, date and quantity of devices returned to sponsor |
|  | 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 IDE authorization/approval, safety reports, etc., is on file |
| [ ]  Yes [ ]  No [ ]  N/A | Investigator maintains proper control of the device under investigation |
| [ ]  Yes [ ]  No [ ]  N/A | Investigator permits an investigational device to be used by subjects only under the investigator’s supervision |
| [ ]  Yes [ ]  No [ ]  N/A | Investigator does not supply an investigational device 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 devices as directed or authorized by the sponsor  |
| [ ]  Yes [ ]  No [ ]  N/A | Investigator reports unanticipated adverse device effects (UADEs) to the IRB and sponsor as soon as possible, but no later than 10 business days after the investigator first learns of the event or sooner if required by sponsor, FDA, etc. |
| [ ]  Yes [ ]  No [ ]  N/A | If PI is sponsor-investigator, he/she conducts an evaluation of the UADE and reports the results of the evaluation to FDA, the reviewing IRB(s), and all participating investigators within 10 business days after first learning or receiving notice of the event |
| [ ]  Yes [ ]  No [ ]  N/A | Investigator reports unanticipated problems that reasonably suggest a HUD has or may have caused or contributed to a subject’s death or serious injury to the IRB and FDA within 48 hours of the investigator first learning of the event. This reporting is in addition to, not a substitute for, FDA and/or manufacturer reporting requirements in accordance with 21 CFR 803.30. |
| [ ]  Yes [ ]  No [ ]  N/A | Investigator promptly reports to the IRB any FDA action regarding death or serious injury related to a HUD |
| [ ]  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 | Protocol changes without prior IRB approval: The investigator notifies sponsor and reviewing IRB of any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency. The notice must be provided as soon as possible but no later than 5 business days after the emergency occurred. If it is not an emergency, prior approval from the sponsor is required for changes in or deviations from the investigational plan. If the change or deviation may affect the scientific soundness of the investigational plan or the rights, safety, or welfare of the subject, the sponsor is required to obtain prior IRB approval and also to obtain FDA approval for a significant risk device investigation by submitting an IDE supplement. |
| [ ]  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 | Reports of emergency use of the investigational device without informed consent: If the investigator uses a device without obtaining informed consent, the investigator reports such use to the sponsor and reviewing IRB within 5 business days after the use occurs. |
| [ ]  Yes [ ]  No [ ]  N/A | Reports of withdrawal of IRB approval: The investigator reports to the sponsor, within 5 business days, a withdrawal of approval by the reviewing IRB of the investigator’s part of an investigation unless required sooner by sponsor. |
| [ ]  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; 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 or the investigator’s part of the investigation. |

For questions, please contact the HRPP Office at HRPP@utsouthwestern.edu or 214-648-3060.