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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](mailto:HRPP@utsouthwestern.edu) or 214-648-3060.