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| The purpose of this checklist is to allow investigators to conduct a quality improvement self-assessment and for QA/QIP staff to conduct a quality improvement assessment of investigators. The investigator is required to compile all applicable documentation in paper or electronic format. | | | |
| Clinical Trials  (Human Subject Research) | | | |
| Principal Investigator | |  | |
| Protocol Name | |  | |
| Name of Person Completing Checklist | |  | |
| Date Completed | |  | |
|  | | | |
| 1. Regulatory Documentation | | | Remarks | |
| ***Research Proposal/Clinical Trial Protocol/Project Plan &Procedures*** | | |  | |
| Yes  No  N/A | Current Version | |  | |
| Yes  No  N/A | Previous Version | |  | |
| Yes  No  N/A | Amendments | |  | |
| Yes  No  N/A | Protocol or Amendment Signature Pages | |  | |
| ***Investigator Brochure (IB)/ Details of* investigational product (drug, supplement, device or other product)** | | |  | |
| Yes  No  N/A | Current Version | |  | |
| Yes  No  N/A | Previous Version | |  | |
| ***FDA 1571 (Only for research involving investigational drugs and biologics)*** | | |  | |
| Yes  No  N/A | Current signed and dated | |  | |
| Yes  No  N/A | Previous signed and dated | |  | |
| ***FDA 1572 (Only for research involving investigational drugs and biologics)*** | | |  | |
| Yes  No  N/A | Current signed and dated | |  | |
| Yes  No  N/A | Previous signed and dated | |  | |
| ***CV/License (current, dated and initialed)/ Bio sketch (Investigator qualifications and training*** | | |  | |
| Yes  No  N/A | Principal Investigator | |  | |
| Yes  No  N/A | Sub-Investigator | |  | |
| Yes  No  N/A | Study Coordinator(s) | |  | |
| Yes  No  N/A | Key Personnel | |  | |
| ***Conflict of Interest (COI)/ Financial Disclosure Certification (FDC)*** | | |  | |
| Yes  No  N/A | Current Version | |  | |
| Yes  No  N/A | Previous Version | |  | |
| ***Informed Consent Form (ICF)(IRB approved and stamped)*** | | |  | |
| Yes  No  N/A | Current Version | |  | |
| Yes  No  N/A | Previous Version | |  | |
| ***Institutional Review Board (IRB)/ Ethics Committee (Approval letters and applications)*** | | |  | |
| Yes  No  N/A | Initial Submission | |  | |
| Yes  No  N/A | Continuing Reviews | |  | |
| Yes  No  N/A | Amendments | |  | |
| Yes  No  N/A | Advertisement, Recruitment Materials | |  | |
| Yes  No  N/A | Patient Materials (education, reminder cards etc.) | |  | |
| Yes  No  N/A | Response to SAE (Serious Adverse Event) | |  | |
| Yes  No  N/A | Investigational New Drug (IND) safety updates reviewed by PI and sent to IRB according to DU guidelines | |  | |
| Yes  No  N/A | Response to IND reports | |  | |
| ***IRB Membership Roster*** | | |  | |
| Yes  No  N/A | Current | |  | |
| Yes  No  N/A | Previous | |  | |
| ***Local and Central laboratory (Only for research involving human specimen test procedures)*** | | |  | |
| Yes  No  N/A | Current Normal Ranges | |  | |
| Yes  No  N/A | Previous Normal Ranges | |  | |
| Yes  No  N/A | Lab Certification (CAP & CLIA) | |  | |
| Yes  No  N/A | Previous Lab Certification | |  | |
| Yes  No  N/A | Lab Director’s CV (Current and previous) | |  | |
| Yes  No  N/A | Lab Director’s license (current and previous) | |  | |
| ***Logs (Journal/Tracking of research activities)*** | | |  | |
| Yes  No  N/A | IRB Submission Log | |  | |
| Yes  No  N/A | Subject Screen/Screen Fail Log | |  | |
| Yes  No  N/A | Subject Randomization Log | |  | |
| Yes  No  N/A | Subject Enrollment Log | |  | |
| Yes  No  N/A | Monitor Visit Log (Initiation to Close-out visit) | |  | |
| Yes  No  N/A | Delegation of Responsibility/Duties/Signature Log | |  | |
| Yes  No  N/A | Training Log | |  | |
| Yes  No  N/A | Data Collection Sheet/Case Report Form(CRF)/eCRF Transmittal (accuracy) Log | |  | |
| Yes  No  N/A | Adverse Event Log | |  | |
| Yes  No  N/A | Protocol Deviation Log | |  | |
| Yes  No  N/A | Investigational Product/Drug Accountability Log | |  | |
| Yes  No  N/A | Maintenance Log (for equipment/supplies provided by sponsor) | |  | |
| Yes  No  N/A | Fund accountability Log | |  | |
| Yes  No  N/A | Subject Payment Accountability Log | |  | |
| Yes  No  N/A | Temperature Log | |  | |
| Yes  No  N/A | Temperature Excursion Log | |  | |
| ***Correspondence*** | | |  | |
| *Study Contacts* |  | |  | |
| Yes  No  N/A | List of Important Study Related Contacts | |  | |
| *IRB* |  | |  | |
| Yes  No  N/A | Interim Report Letters | |  | |
| Yes  No  N/A | Notifications of IRB (disapproval, deferral, modifications) | |  | |
| Yes  No  N/A | Responses to IRB actions | |  | |
| *Sponsor/CRO* |  | |  | |
| Yes  No  N/A | Letters | |  | |
| Yes  No  N/A | Meeting Notes | |  | |
| *Research Team* |  | |  | |
| Yes  No  N/A | Letters | |  | |
| Yes  No  N/A | Meeting Notes | |  | |
| *General* |  | |  | |
| Yes  No  N/A | Substantial (E-mail/Telephone) Correspondence (IRB, Sponsor/CRO, Research team/subjects, etc.) | |  | |
| ***Adverse Events/Serious Adverse Events (AEs/SAEs)*** | | |  | |
| Yes  No  N/A | All AEs/SAEs identified | |  | |
| Yes  No  N/A | Recording AEs/SAEs per guidelines and protocol | |  | |
| Yes  No  N/A | All SAEs reported | |  | |
| Yes  No  N/A | Completed SAE Reports (final reports or notes of their location) | |  | |
| Yes  No  N/A | IND safety letters | |  | |
| ***Case Report Form (CRF)/ Data collection sheet/ Survey/Questionnaire*** | | |  | |
| Yes  No  N/A | Copy of sample CRF | |  | |
| ***Investigational Product (IP)* (Drug, supplement, device or other product)** | | |  | |
| Yes  No  N/A | Instruction for handling IP | |  | |
| Yes  No  N/A | IP receipt/packing records | |  | |
| Yes  No  N/A | IP Accountability form | |  | |
| Yes  No  N/A | IP Supply forms | |  | |
| Yes  No  N/A | IVRS/IXRS (interactive voice/Web response system) worksheets/receipts | |  | |
| ***Specimen Storage*** | | |  | |
| Yes  No  N/A | Securely stored | |  | |
| Yes  No  N/A | Labeled per study plan/procedures | |  | |
| ***Document Retention*** | | |  | |
| Yes  No  N/A | Signed and dated HIPAA authorizations and consent documents that include HIPAA authorizations are retained for 7 years after completion of the research | |  | |
| Yes  No  N/A | Human subject research and regulatory records retained 3 years after completion the research or period specified in protocol/agreements/FDA requirements | |  | |
| Yes  No  N/A | Pediatric research records retained until the youngest subject turns twenty-five years old | |  | |
| Yes  No  N/A | Records for sponsored trial retained until the sponsor authorized destruction of the records. | |  | |
| ***Miscellaneous*** | | |  | |
| Yes  No  N/A | Decoding procedures for randomized and blinded trials | |  | |
| Yes  No  N/A | Is PI aware of HRP-104 “Brochure: Should I take part in Research?” | |  | |
| Yes  No  N/A | Has PI used or shared HRP 104 “Brochure: Should I take part in Research?” with subjects or research team? | |  | |
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| 1. Chart Review | | | **Remarks** | |
| ***Informed Consent Form (ICF)*** | | |  | |
| Yes  No  N/A | IRB approved ICFs used to enroll human subjects, with appropriate signatures and dates | |  | |
| Yes  No  N/A | Informed consent process documentation | |  | |
| Yes  No  N/ | ICFs from previous approval periods with appropriate signatures/dates | |  | |
| Yes  No  N/A | Informed consent process documentation for re-consenting | |  | |
| Yes  No  N/A | ICF dates prior to study specific procedures performed | |  | |
| ***Eligibility Criteria*** | | |  | |
| Yes  No  N/A | Inclusion/Exclusion Criteria checklist completed | |  | |
| Yes  No  N/A | Eligibility criteria documented and met | |  | |
| ***Investigational Product (IP)* (Drug, supplement, device or other product)** | | |  | |
| Yes  No  N/A | Administered as per protocol | |  | |
| Yes  No  N/A | Documented as per protocol | |  | |
| ***Case Report Form (CRF)/ Data collection sheet/Survey***/***Questionnaire*** | | |  | |
| Yes  No  N/A | CRF/eCRF completed timely | |  | |
| Yes  No  N/A | CRF/eCRF consistent with source documentation | |  | |
| Yes  No  N/A | Proper Documentation in CRFs Transmission | |  | |
| Yes  No  N/A | All queries answered in 30 days | |  | |
| Yes  No  N/A | Error corrections properly executed | |  | |
| Yes  No  N/A | Review of day one CRF and random interim CRF | |  | |
| ***Adverse Events (AEs)/Serious Adverse Events(SAEs)*** | | |  | |
| Yes  No  N/A | Recording of AEs as per guidelines and protocol | |  | |
| Yes  No  N/A | All AEs identified and reported | |  | |
| Yes  No  N/A | All SAEs identified and reported | |  | |
| ***Protocol Deviations*** | | |  | |
| Yes  No  N/A | Protocol deviations identified and reported | |  | |
| Yes  No  N/A | IRB submission of protocol deviations (according to requirements) documented | |  | |
| *Subject Payment* |  | |  | |
| Yes  No  N/A | Number and amount of payments to each subject (Cash/Gift cards/Gift certificates) | |  | |