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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) |  |