**STUDY AUDIT CHECKLIST**

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| Principal Investigator: |  | Contact Person(if different from PI): |  |
| Employee/Student#: |  | Phone: |  | Employee/Student#: |  | Phone: |  |
| Email: |  | Email: |  |
| Department: |  | Department: |  |
| Campus Address*:* |  | Campus Address: |  |
| Co-Investigator(s)(Name & affiliation or “None”): |  |
| Title of Study: |  |

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| **STUDY STATUS:** |  |
| **#SUBJECTS ENROLLED:** |  |
| **LOCATION OF STUDY:** |  |
| **ALL SITES PI IS DIRECTLY RESPONSIBLE** |  |
| **DATE OF AUDIT:** |  |
| **AUDITOR:** |  |

**Audit worksheets completed for this audit:**

* 1. Regulatory Documentation
* 2. Site Operations
* 3. Protocol Compliance
* 4. Informed Consent Documentation
* 5. Subject Records
* 6. Safety Monitoring
* 7. Drug/Device/Test Article Accountability

# **AUDIT WORKSHEET 1**

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| Auditor:  |  | Date: |  | IRB# |  |

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| **REGULATORY DOCUMENTATION** |

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| 1. Regulatory documents organized, complete, available: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 2. Protocol, current IRB approved version in study file: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 3. Informed Consent Documents (ICD), current IRB-approved version in study file: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 4. Parental Permission Documents, current IRB-approved version in study file: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 5. Assent Document current IRB-approved version in study file: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 6. IDE application/approval: [ ]  Yes [ ]  No [ ]  N/AComments: |
| 7. Investigator Brochure/Device Manual in study file: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 8. IND application/approval: [ ]  Yes [ ]  No [ ]  N/AComments: |
| 9. Food & Drug Administration (FDA) 1571 current, signed, dated, and completed: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 10. All sub-investigators listed on FDA 1572 current, signed, dated, and completed: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 11. All sub-investigators listed on FDA 1572: [ ]  Yes [ ]  No [ ]  N/AComments: |
| 12. Required Curriculum Vitaes (CV) on file (investigators and sub-investigator listed on FDA 1572): [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 13. Clinical laboratory certifications on file: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 14. Laboratory normals on file: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 15. Site signature log in study file: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 16. Subject enrollment screening log in study file: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 17. Staff training records in study file: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 18. Sponsor correspondence in study file: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 19. Sponsor monitoring log/reports in study file: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 20. FDA and all study related correspondence in file: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 21. Questionnaire/survey/advertisements/current IRB approved version in study file: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 22. All amendments/modifications/addendums to originally approved protocol or ICD in study file:  [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 23. Waiver or modification of consent and authorization (HIPAA) current IRB approved version in study file: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 24. All correspondence (e.g., letters, e-mail, ect..) to and from the IRB on file: [ ]  Yes [ ]  No [ ]  N/AComments: |
| 25. Annual IRB continuing renewal application review obtained: [ ]  Yes [ ]  No [ ]  N/AComments:  |

# **AUDIT WORKSHEET 2**

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| Auditor:  |  | Date: |  | IRB# |  |

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| **SITE OPERATIONS** |

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| 1. Documentation of P.I./Co-P.I. involvement in conducting and supervising study: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 2. Responsibilities and tasks delegated to qualified personnel: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 3. P.I./Co-P.I. directly involved in the ICD process: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 4. P.I./Co-P.I. or study personnel delegate available by phone 24 hours/day to study participants: [ ] Yes [ ] No [ ] N/AComments:  |
| 5. Process in place to maintain study subject confidentiality: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 6. All investigators and study personnel completed required research training: [ ]  Yes [ ]  No [ ]  N/AComments:  |

# **AUDIT WORKSHEET 3**

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| Auditor:  |  | Date: |  | IRB# |  |

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| **PROTOCOL COMPLIANCE** |

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| 1. Inclusion/Exclusion criteria met per IRB approved protocol: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 2. Screening, study treatment/procedures, performed per IRB approved protocol: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 3. Study administered by IRB authorized personnel only and at approved sites: [ ]  Yes [ ]  No [ ]  N/A(Look for signatures or notes by personnel not on the list, especially in CRFs)Comments:  |
| 4. Only IRB protocol approved concomitant – treatment or medications administered: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 5. Modifications to the study protocol prior to IRB approval or exemption: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 6. IRB approved study protocol follow-up procedures performed: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 7. Drug, Device or test article administration errors: [ ]  Yes [ ]  No [ ]  N/AComments:  |

# **AUDIT WORKSHEET 4**

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| Auditor:  |  | Date: |  | IRB# |  |

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| **INFORMED CONSENT DOCUMENTATION** |

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| 1. IRB stamped ICD correct current version used and in study file: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 2. ICD in each patients source document/medical record: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 3. ICD’s signed, dated and witnessed: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 4. Parental permission/authorization document signed, dated and witnessed: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 5. Assent document signed dated and witnessed: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 6. Consent process documented in source document/progress notes: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 7. Consent obtained prior to study procedures/and or screening as applicable: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 8. Subject or legally authorized representative provided with a copy of the consent document: [ ]  Yes [ ]  No [ ]  N/AComments: |
| 9. All additional consent documents signed, dated and witnessed. (e.g., consent to collect/ take/ store, specimens, audio/video images: [ ]  Yes [ ]  No [ ]  N/AComments:  |

# **AUDIT WORKSHEET 5**

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| Auditor:  |  | Date: |  | IRB# |  |

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| **SUBJECT RECORDS** |

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| 1. Subject records/source documents organized, readable and secured.: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 2. Subject case history documented to include information, data, and observations of subjects condition at time of enrollment: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 3. Study events and progress notes on the conditions of the subject throughout participation in the study: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 4. Data collected in source documents are also recorded on Case Report forms as appropriate or equivalent record: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 5. Direct Data entry system is thorough, accurate, complete and captures study events: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 6. All copies correspondence with the subject is in the official record: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 7. Information, data, observation of subjects condition at end of study: [ ]  Yes [ ]  No [ ]  N/AComments:   |
| 8. Subject withdrawal form research participation including reason documented: [ ]  Yes [ ]  No [ ]  N/AComments: |
| 9. Subject compensation is documented and concurs with the IRB approval for compensation in the informed consent document: [ ]  Yes [ ]  No [ ]  N/AComments: |

# **AUDIT WORKSHEET 6**

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| Auditor:  |  | Date: |  | IRB# |  |

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| **SAFETY MONITORING** |

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| 1.All Adverse Events (AE) reported to the IRB sponsor and appropriate regulatory agency within required timeline requirements: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 2. Serious Adverse Events (SAE) followed to resolution, return to baseline, completion, or judged acceptable by the IRBs and Principal Investigator: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 3. All adverse events recorded in subjects record, source document, and CRF or equivalent: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 4. All protocol deviations reported to the IRB, Sponsor and appropriate regulatory agency within required timeline: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 5. All Data Safety Monitoring Board (DSMB) reports sent to the IRB: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 6. IRB notified of unanticipated problems involving risk to subjects at site: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 7. All External SAE, Safety Reports and Med Watch-reports submitted to the IRB within required timeline: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 8. Periodic Progress reports sent to the IRB if applicable: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 9. IRB approval of any changes in research activity as required by regulations and guidelines: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 15. All correspondence (e.g., e-mail, letters) to and from the IRB on file: [ ]  Yes [ ]  No [ ]  N/A Comments: |

# **AUDIT WORKSHEET 7**

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| Auditor:  |  | Date: |  | IRB# |  |

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| **DRUG/DEVICE/TEST ARTICLE ACCOUNTABILITY** |

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| 1. Records of receipt of drug/device/test articles in study file: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 2. All drugs/devices/test articles secured and stored properly (i.e. temperature log, light protections, etc. as per the IDDF):Comments: [ ]  Yes [ ]  No [ ]  N/A |
| 3. Inventory Log – organized, completed, available: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 4. Drug/device/test article name, dosage strength, and form type: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 5. Lot number [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 6. Expiration date: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 7. Date and quantity dispensed: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 8. Amount transferred/returned/destroyed: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 9. Date and quantity returned by study participant: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 10. Date and quantity returned to sponsor:: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 11. 24 hour emergency telephone number of Sponsor: [ ]  Yes [ ]  No [ ]  N/A(Call and see who answers. Is it still the same as the number listed in the IDDF?)Comments:  |
| 12. Chain of custody per regulations or protocol: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 13. Drug/device/test article used for protocol purposes only: [ ]  Yes [ ]  No [ ]  N/AComments:  |
| 14. Drug/device/test article manual/package insert information in file: [ ]  Yes [ ]  No [ ]  N/A Comments:  |