INSTITUTIONAL REVIEW BOARD
THE UNIVERSITY OF UTAH
75 South 2000 East Salt Lake City, UT 84112 | 801.581.3655 | IRB@utah.edu

STUDY AUDIT CHECKLIST

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:							

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

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AUDIT WORKSHEET 1

Auditor:		Date:		IRB#	

REGULATORY DOCUMENTATION

1. Regulatory documents organized, complete, available: Comments:	☐ Yes ☐ No ☐ N/A
2. Protocol, current IRB approved version in study file: Comments:	☐ Yes ☐ No ☐ N/A
3. Informed Consent Documents (ICD), current IRB-approved version in study file: Comments:	☐ Yes ☐ No ☐ N/A
4. Parental Permission Documents, current IRB-approved version in study file: Comments:	☐ Yes ☐ No ☐ N/A
5. Assent Document current IRB-approved version in study file: Comments:	☐ Yes ☐ No ☐ N/A
6. IDE application/approval: Comments:	☐ Yes ☐ No ☐ N/A
7. Investigator Brochure/Device Manual in study file: Comments:	☐ Yes ☐ No ☐ N/A

8. IND application/approval: ☐ Yes ☐ No ☐ N/A Comments:
9. Food & Drug Administration (FDA) 1571 current, signed, dated, and completed: ☐ Yes ☐ No ☐ N/A Comments:
10. All sub-investigators listed on FDA 1572 current, signed, dated, and completed: ☐ Yes ☐ No ☐ N/A Comments:
11. All sub-investigators listed on FDA 1572: ☐ Yes ☐ No ☐ N/A Comments:
12. Required Curriculum Vitaes (CV) on file (investigators and sub-investigator listed on FDA 1572): ☐ Yes ☐ No ☐ N/A Comments:
13. Clinical laboratory certifications on file: ☐ Yes ☐ No ☐ N/A Comments:
14. Laboratory normals on file: ☐ Yes ☐ No ☐ N/A Comments:

15. Site signature log in study file: Comments:	☐ Yes ☐ No ☐ N/A
16. Subject enrollment screening log in study file: Comments:	☐ Yes ☐ No ☐ N/A
17. Staff training records in study file: Comments:	☐ Yes ☐ No ☐ N/A
18. Sponsor correspondence in study file: Comments:	☐ Yes ☐ No ☐ N/A
19. Sponsor monitoring log/reports in study file: Comments:	☐ Yes ☐ No ☐ N/A
20. FDA and all study related correspondence in file: Comments:	☐ Yes ☐ No ☐ N/A
21. Questionnaire/survey/advertisements/current IRB approved version in study file: Comments:	☐ Yes ☐ No ☐ N/A
22. All amendments/modifications/addendums to originally approved protocol or ICD in study file: Comments:	☐ Yes ☐ No ☐ N/A

23. Waiver or modification of consent and authorization (HIPAA) current IRB approved version in study file: ☐ Yes ☐ No ☐ N/A Comments:
24. All correspondence (e.g., letters, e-mail, ect..) to and from the IRB on file: ☐ Yes ☐ No ☐ N/A Comments:
25. Annual IRB continuing renewal application review obtained: ☐ Yes ☐ No ☐ N/A Comments:

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AUDIT WORKSHEET 2

Auditor:		Date:		IRB#	

SITE OPERATIONS

1. Documentation of P.I./Co-P.I. involvement in conducting and supervising study: ☐ Yes ☐ No ☐ N/A
Comments:

2. Responsibilities and tasks delegated to qualified personnel: ☐ Yes ☐ No ☐ N/A
Comments:

3. P.I./Co-P.I. directly involved in the ICD process: ☐ Yes ☐ No ☐ N/A
Comments:

4. P.I./Co-P.I. or study personnel delegate available by phone 24 hours/day to study participants: ☐ Yes ☐ No ☐ N/A
Comments:

5. Process in place to maintain study subject confidentiality: ☐ Yes ☐ No ☐ N/A
Comments:

6. All investigators and study personnel completed required research training: ☐ Yes ☐ No ☐ N/A
Comments:

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AUDIT WORKSHEET 3

Auditor:		Date:		IRB#	

PROTOCOL COMPLIANCE

1. Inclusion/Exclusion criteria met per IRB approved protocol: ☐ Yes ☐ No ☐ N/A
Comments:

2. Screening, study treatment/procedures, performed per IRB approved protocol: ☐ Yes ☐ No ☐ N/A
Comments:

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/A
Comments:

5. Modifications to the study protocol prior to IRB approval or exemption: ☐ Yes ☐ No ☐ N/A
Comments:

6. IRB approved study protocol follow-up procedures performed: ☐ Yes ☐ No ☐ N/A
Comments:

7. Drug, Device or test article administration errors: ☐ Yes ☐ No ☐ N/A
Comments:

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AUDIT WORKSHEET 4

Auditor:		Date:		IRB#	

INFORMED CONSENT DOCUMENTATION

1. IRB stamped ICD correct current version used and in study file: ☐ Yes ☐ No ☐ N/A
Comments:

2. ICD in each patients source document/medical record: ☐ Yes ☐ No ☐ N/A
Comments:

3. ICD's signed, dated and witnessed: ☐ Yes ☐ No ☐ N/A
Comments:

4. Parental permission/authorization document signed, dated and witnessed: ☐ Yes ☐ No ☐ N/A
Comments:

5. Assent document signed dated and witnessed: ☐ Yes ☐ No ☐ N/A
Comments:

6. Consent process documented in source document/progress notes: ☐ Yes ☐ No ☐ N/A
Comments:

7. Consent obtained prior to study procedures/and or screening as applicable: ☐ Yes ☐ No ☐ N/A
Comments:

8. Subject or legally authorized representative provided with a copy of the consent document: ☐ Yes ☐ No ☐ N/A
Comments:

9. All additional consent documents signed, dated and witnessed. (e.g., consent to collect/ take/ store, specimens, audio/video images: ☐ Yes ☐ No ☐ N/A
Comments:

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AUDIT WORKSHEET 5

Auditor:		Date:		IRB#	

SUBJECT RECORDS

1. Subject records/source documents organized, readable and secured.: ☐ Yes ☐ No ☐ N/A
Comments:

2. Subject case history documented to include information, data, and observations of subjects condition at time of enrollment: ☐ Yes ☐ No ☐ N/A
Comments:

3. Study events and progress notes on the conditions of the subject throughout participation in the study: ☐ Yes ☐ No ☐ N/A
Comments:

4. Data collected in source documents are also recorded on Case Report forms as appropriate or equivalent record: ☐ Yes ☐ No ☐ N/A
Comments:

5. Direct Data entry system is thorough, accurate, complete and captures study events: ☐ Yes ☐ No ☐ N/A
Comments:

6. All copies correspondence with the subject is in the official record: ☐ Yes ☐ No ☐ N/A
Comments:

7. Information, data, observation of subjects condition at end of study: ☐ Yes ☐ No ☐ N/A
Comments:

8. Subject withdrawal form research participation including reason documented: ☐ Yes ☐ No ☐ N/A
Comments:

9. Subject compensation is documented and concurs with the IRB approval for compensation in the informed consent document: ☐ Yes ☐ No ☐ N/A
Comments:

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AUDIT WORKSHEET 6

Auditor:		Date:		IRB#	

SAFETY MONITORING

1.All Adverse Events (AE) reported to the IRB sponsor and appropriate regulatory agency within required timeline requirements:

☐ Yes ☐ No ☐ N/A

Comments:

2. Serious Adverse Events (SAE) followed to resolution, return to baseline, completion, or judged acceptable by the IRBs and Principal Investigator: ☐ Yes ☐ No ☐ N/A

Comments:

3. All adverse events recorded in subjects record, source document, and CRF or equivalent:

☐ Yes ☐ No ☐ N/A

Comments:

4. All protocol deviations reported to the IRB, Sponsor and appropriate regulatory agency within required timeline:

☐ Yes ☐ No ☐ N/A

Comments:

5. All Data Safety Monitoring Board (DSMB) reports sent to the IRB: ☐ Yes ☐ No ☐ N/A

Comments:

6. IRB notified of unanticipated problems involving risk to subjects at site: ☐ Yes ☐ No ☐ N/A
Comments:

7. All External SAE, Safety Reports and Med Watch-reports submitted to the IRB within required timeline:
☐ Yes ☐ No ☐ N/A
Comments:

8. Periodic Progress reports sent to the IRB if applicable: ☐ Yes ☐ No ☐ N/A
Comments:

9. IRB approval of any changes in research activity as required by regulations and guidelines: ☐ Yes ☐ No ☐ N/A
Comments:

15. All correspondence (e.g., e-mail, letters) to and from the IRB on file: ☐ Yes ☐ No ☐ N/A
Comments:

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AUDIT WORKSHEET 7

Auditor:		Date:		IRB#	

DRUG/DEVICE/TEST ARTICLE ACCOUNTABILITY

1. Records of receipt of drug/device/test articles in study file: ☐ Yes ☐ No ☐ N/A
Comments:

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/A
Comments:

4. Drug/device/test article name, dosage strength, and form type: ☐ Yes ☐ No ☐ N/A
Comments:

5. Lot number ☐ Yes ☐ No ☐ N/A
Comments:

6. Expiration date: ☐ Yes ☐ No ☐ N/A
Comments:

7. Date and quantity dispensed: ☐ Yes ☐ No ☐ N/A
Comments:

8. Amount transferred/returned/destroyed: Comments:	☐ Yes ☐ No ☐ N/A
9. Date and quantity returned by study participant: Comments:	☐ Yes ☐ No ☐ N/A
10. Date and quantity returned to sponsor:: Comments:	☐ Yes ☐ No ☐ N/A
11. 24 hour emergency telephone number of Sponsor: (Call and see who answers. Is it still the same as the number listed in the IDDF?) Comments:	☐ Yes ☐ No ☐ N/A
12. Chain of custody per regulations or protocol: Comments:	☐ Yes ☐ No ☐ N/A
13. Drug/device/test article used for protocol purposes only: Comments:	☐ Yes ☐ No ☐ N/A
14. Drug/device/test article manual/package insert information in file: Comments:	☐ Yes ☐ No ☐ N/A