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STUDY 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. Site Operations
- ☐ 2. Protocol Compliance
- ☐ 3. Informed Consent Documentation
- ☐ 4. Subject Records

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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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PROTOCOL COMPLIANCE

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

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INFORMED CONSENT DOCUMENTATION

1. IRB stamped ICD correct current version used and in study file: Comments:	☐ Yes ☐ No ☐ N/A
2. ICD in each patients source document/medical record: Comments:	☐ Yes ☐ No ☐ N/A
3. ICD's signed, dated and witnessed: Comments:	☐ Yes ☐ No ☐ N/A
4. Parental permission/authorization document signed, dated and witnessed: Comments:	☐ Yes ☐ No ☐ N/A
5. Assent document signed dated and witnessed: Comments:	☐ Yes ☐ No ☐ N/A
6. Consent process documented in source document/progress notes: Comments:	☐ Yes ☐ No ☐ N/A
7. Consent obtained prior to study procedures/and or screening as applicable: Comments:	☐ Yes ☐ No ☐ N/A

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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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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:

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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: