

MUSC and VA Study Audit Checklist

PROTOCOL: _____ **HR#** _____
DATE: _____
INVESTIGATOR: _____
AUDITOR: _____
STUDY STATUS: _____
SUBJECTS ENROLLED: _____

This audit consisted of reviewing the following activities:

- % () Informed consent documents reviewed.
- % () Of subject's research charts reviewed.
- Serious adverse events reported to the IRB for this study.
- Regulatory documents pertaining to this study reviewed.

The results of this audit are as follows:

<u>1. PATIENT CONSENT ISSUES</u>	YES	NO	N/A
1.1 Informed Consent Document (ICD) found at facility for each patient	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.1.1 ICD found in each medical record	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.2 ICDs signed, dated, and witnessed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.3 Institutional Review Board (IRB) stamped ICD used (correct current version)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.4 Consent obtained prior to study procedures and/or screening, as applicable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.5 Payments to patient per protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.6 Consent documented in progress notes/source documents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

NOTE: Any "NO" requires comment

Specific counts for Items 1.1 – 1.6

# subjects for whom ICD were found at site	_____ (1.1)
# ICDs reviewed in detail	_____ (1.1, 1.2, 1.3, 1.4)
# ICDs with no deficiencies	_____ (1.2, 1.3, 1.4)
# wrong version used	_____ (1.3)
# consents obtained late	_____ (1.4)
# not properly witnessed	_____ (1.2)
# deficiencies in dating & signing	_____ (1.2)
# with other deficiencies	_____ (1.2, 1.3, 1.4, 1.6)

COMMENTS:

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<u>2. PROTOCOL ADHERENCE</u>	YES	NO	N/A
2.1 Inclusion/Exclusion (I/E) criteria met per protocol or an IRB authorization is obtained for the deviation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.2 Procedures performed per the protocol or an IRB authorization is obtained for the deviation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.3 Only the concomitant therapy authorized in protocol used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

NOTE: Any "NO" requires comment

Specific counts for Items 2.1 – 2.4.

total subjects evaluated _____

total subjects meeting all I/Es criteria _____ (2.1)

of instances or procedures not done and exemption not authorized _____ (2.2)

of subjects receiving inappropriate/unauthorized drug _____ (2.3)

of instances of other unauthorized non-adherence _____ (2.4)

COMMENTS:

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<u>3. SAFETY MONITORING</u>	YES	NO	N/A
3.1 All Adverse Events (AE) recorded on Case Report Forms (CRF) or equivalent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.2 Serious Adverse Events (SAE) reported to IRB and Sponsor per timeline requirements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.3 SAEs followed to resolution, return to baseline, completion, or judged acceptable to Principal Investigator (PI)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

NOTE: Any "NO" requires comment

Specific counts for Items 3.1 – 3.2

AEs found in record, but not on CRF _____ (3.1)
of SAEs not reported to IRB/Sponsor _____ (3.2)
of SAEs not reported within time frame _____ (3.2)
(if able to determine when site became aware)

COMMENTS:

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4. INSTITUTIONAL REVIEW BOARD YES NO N/A

REQUIRED IRB APPROVALS:

- | | | | |
|---|--------------------------|--------------------------|--------------------------|
| 4.1 IRB approval of protocol and ICD obtained | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.1.1 Documentation of approval(s) in study file | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.2 IRB approval of amendments to protocol & ICD obtained | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.2.1 Documentation of approval(s) in study file | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.3 IRB approval of advertising & other patient information obtained | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.3.1 Documentation of approval(s) in study file | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.4 Annual IRB review obtained | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.4.1 Documentation of approval(s) in study file | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.5 IRB uses a date stamp or equivalent to indicate document approval | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.6 Expedited review process used by site | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

REQUIRED IRB NOTIFICATIONS:

- | | | | |
|--|--------------------------|--------------------------|--------------------------|
| 4.7 IRB notified of unanticipated problems involving risk, (e.g., SAEs at site) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.7.1 IRB notified of Safety Reports received from Sponsor | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.7.2 SAEs and Safety Reports submitted to IRB within required timeline | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.8 Periodic progress reports submitted to IRB, if applicable | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.9 IRB notified of changes in research activity and other items as required by regulations or local IRB | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

NOTE: Any "NO" requires comment

Specific counts for Items 4.7

- | | | |
|---|-------|---------|
| # of SAEs not reported to IRB | _____ | (4.7) |
| # of Sponsor Safety Reports not reported to IRB | _____ | (4.7.1) |
| # of late IRB submissions of SAEs & Safety Reports
(if able to determine when site became aware) | _____ | (4.7.2) |

COMMENTS:

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<u>5A. ESSENTIAL DOCUMENTS (STUDY FILE)</u>	YES	NO	N/A
REGULATORY DOCUMENTATION:			
5.1 Regulatory documents organized, complete, available	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.2 Food and Drug Administration (FDA) 1572 current, signed, dated, and complete	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.2.1 All sub-investigators listed on FDA 1572	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.3 Required Curriculum Vitae (CV) on file (investigators and sub-investigator listed on FDA 1572)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.4 Protocol, operations manual, and ICD available and current	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.4.1 Adequate version control maintained for documents (prior versions in study file)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.5 Clinical laboratory certifications on file	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.5.1 Laboratory normals on file	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.6 Current Investigator's Brochure on file	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.7 Site signature log in study file	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.8 Subject enrollment log in study file	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.9 Staff training records in study file	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.10 All study related correspondence in study file	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.11 Current IRB letter of assurance in study file	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

NOTE: Any "NO" requires comment

COMMENTS:

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5B. ESSENTIAL DOCUMENTS (STUDY FILE) CON'T YES NO N/A

PATIENT RECORDS:

5.12 Study events noted in subject's official medical record (e.g., enrollment, consent, study drug involved, SAE, study completion)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.13 Clinical warning placed in electronic records of study patients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.14 CRF completion current (or CRF equivalent)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.14.1 Data corrections made appropriately	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.15 Case histories adequate and accurate (global impression)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.15.1 CRF data supported by source documents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.15.2 Data found in source documents are also recorded on CRFs (e.g., concurrent meds, AEs, SAEs, and intercurrent illnesses, if required by this trails CRFs)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.15.3 Patient records are readily available	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.15.4 Clinical laboratory results documented and available	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.15.5 Dropouts and reasons recorded (e.g., listed/documentated in study file)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

NOTE: Any "NO" requires comment

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<u>6. DRUG/DEVICE ACCOUNTABILITY/HANDLING</u>	YES	NO	N/A
6.1 Adequate records of receipt	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.2 Adequate records of dispensing, returns, and/or destruction	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.3 Adequate documentation of transfer (e.g., chain of custody)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.4 Custody is per protocol or regulations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.5 Storage conditions/monitoring methods (if any) are per protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.6 Drug/device used for protocol purposes only (must have IRB authorization for non-protocol use)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

NOTE: Errors in dispensing or administration of drugs/devices should be considered a protocol violation and documented in Section 2

NOTE: Any "NO" requires comment

COMMENTS:

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<u>7. SITE OPERATIONS/ PI INVOLVEMENT</u>	YES	NO	N/A
7.1 Appropriate delegation of authority	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1.1 Tasks and responsibilities delegated to qualified personnel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1.2 Adequate investigator involvement in conducting or supervising trial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1.3 Investigator's role in consent process is per protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2 Properly documented transfer of responsibility (specific tasks and personnel)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.3 Subjects not participating in simultaneous interventional trials	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.4 Patients not receiving simultaneous investigational drugs (FDA concern)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.5 Site has copy of IRB rules (hard copy or electronic)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.6 Site operates under written Standard Operating Procedures (SOP), if applicable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

NOTE: Any "NO" requires comment

COMMENTS: