SAMPLE AUDIT CHECKLIST

FOR USE BY INDIVIDUAL(S) CONDUCTING THE AUDIT

A. REGULATORY DOCUMENTATION

1. Is the approved protocol on file? (Original and all previously approved versions?)	☐ Yes	☐ No	
1.1 Is the IRB Approval Letter(s) on file?	☐ Yes	☐ No	
1.2 Is this an FDA regulated study? (If no, go to 1.3)	☐ Yes	☐ No	☐ N/A
1.2.1 Is there a signed FDA 1572 on file?	☐ Yes	☐ No	
1.2.2 Are all versions of the Investigator Brochure or package insert on file?	☐ Yes	☐ No	
1.2.3 Are all versions of the package insert or device manual on file?	☐ Yes	☐ No	
1.2.4 Is all correspondence to and from the FDA on file?	☐ Yes	☐ No	
1.3 CVs of PI/Co-PI and all study staff on file?	☐ Yes	☐ No	☐ N/A
1.3.1 For all CVs on file, are they current in alignment with applicable requirements?	☐ Yes	☐ No	
1.3.2 For all CVs on file, are they signed and dated, if required?	☐ Yes	☐ No	
1.3.3 Is there a staff training log?	☐ Yes	☐ No	
1.3.4 Is the staff training log complete and up-to-date?	☐ Yes	☐ No	
1.4 Is there a subject enrollment log?	☐ Yes	☐ No	
1.4.1 Is the subject enrollment log complete?	☐ Yes	☐ No	
1.5 Is/will the site (be) monitored?	☐ Yes	☐ No	
1.5.1 Who is the monitoring body? _____			
1.5.2 How often? _____			
1.5.3 Is there a monitoring log?	☐ Yes	☐ No	
1.5.4 If yes, is the monitoring log complete?	☐ Yes	☐ No	
1.6 Is there a staff signature and delegation of responsibilities log?	☐ Yes	☐ No	☐ N/A
1.6.1 Is the staff signature and delegation log complete and up-to-date?	☐ Yes	☐ No	
1.7 Is all correspondence to and from the sponsor on file?	☐ Yes	☐ No	☐ N/A
1.8 Are lab tests required?	☐ Yes	☐ No	☐ N/A
1.8.1 If yes, is a copy of normal lab values on file?	☐ Yes	☐ No	
1.8.2 Is a copy of the lab certification on file?	☐ Yes	☐ No	

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REGULATORY DOCUMENTS COMMENTS/ISSUES:

B. SUBJECT RECRUITMENT PROCEDURES

2. How are participants identified for the study?_____

2.0.1 Are there recruitment materials for this study? ☐ Yes ☐ No

2.0.2 Are all recruitment materials IRB approved? ☐ Yes ☐ No

2.0.3 Are all currently approved recruitment materials on file? ☐ Yes ☐ No

SUBJECT RECRUITMENT PROCEDURES COMMENTS/ISSUES:

C. INFORMED CONSENT PROCESS

☐ Section not applicable (consent waived)

3. Is written consent required to be obtained by the IRB approved protocol? ☐ Yes ☐ No

3.1 If yes, how many versions of the consent form are there? _____

DATE APPROVED	EXPIRATION DATE	MASTER COPY OF APPROVED CONSENT FORM ON FILE? (Y/N)

3.2 Have any eligible subjects been enrolled in this study? ☐ Yes ☐ No

(If no, skip the remaining questions in this section and D. SUBJECT SELECTION)

For the consent forms and documentation reviewed, complete the following questions:

3.3 How many subjects are/were enrolled to date? _____

3.4 How many subjects is/was the site approved to enroll? _____

3.5 How many subjects were chosen for review? _____

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3.6 Did each subject or their LAR sign his/her own consent form? ☐ Yes ☐ No

3.7 Did each subject date his/her own consent form? ☐ Yes ☐ No

3.8 Was the current approved consent document used for each subject? ☐ Yes ☐ No

3.9 Are any participants minors? *(If yes, answer the following; if no, go to 3.10)* ☐ Yes ☐ No

3.9.1 Is there evidence of assent? ☐ Yes ☐ No

3.9.2 Did the parent(s) or guardian sign and date properly? ☐ Yes ☐ No

3.10 Did the study staff sign the consent? ☐ Yes ☐ No

3.11 Did the signing study staff date the signed consent? ☐ Yes ☐ No

3.12 Did anyone not approved by the IRB to consent subjects sign as study representative? ☐ Yes ☐ No

3.12.1 If yes, who?_____

3.13 Does the signature date prior to all approved research procedures? ☐ Yes ☐ No

3.14 Did each subject receive a copy of the signed and dated consent form? ☐ Yes ☐ No

3.15 Is subject's receipt of a copy of the signed consent form documented? ☐ Yes ☐ No

3.16 If consent was revised were subject re-consented or notified as required by the IRB? ☐ Yes ☐ No

INFORMED CONSENT PROCESS COMMENTS/ISSUES:

D. SUBJECT SELECTION

☐ Section not applicable (no subjects enrolled)

4. Is there documentation of subject eligibility (note format used)? ☐ Yes ☐ No

4.1 Did all subjects meet eligibility criteria? ☐ Yes ☐ No

4.2 If no, were they excluded appropriately? ☐ Yes ☐ No

4.2.1 If no, was a protocol deviation submitted to the IRB? ☐ Yes ☐ No

SUBJECT SELECTION COMMENTS/ISSUES:

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E. IRB REPORTING AND OVERSIGHT

5. Were study procedures conducted following initial IRB approval? ☐ Yes ☐ No

5.1 Were changes to study procedures only implemented after IRB approval was received? ☐ Yes ☐ No

5.2 Were study procedures conducted during a period of expiration or suspension? ☐ Yes ☐ No

IRB REPORTING AND OVERSIGHT COMMENTS/ISSUES:

F. STUDY CONDUCT

6. Were study assessments/evaluations performed according to protocol? ☐ Yes ☐ No

6.1 Were study tests/procedures completed at the time intervals described in the protocol? ☐ Yes ☐ No

STUDY CONDUCT COMMENTS/ISSUES:

G. ADVERSE EVENTS

7. Were adverse events monitored and recorded as described in protocol and Reviewing IRB's policies and assessed by appropriately qualified and delegated individuals in a timely manner? ☐ Yes ☐ No

ADVERSE EVENTS COMMENTS/ISSUES:

H. DATA MANAGEMENT & SECURITY

8. Is source documentation and data collection accurate, complete and appropriately transcribed? ☐ Yes ☐ No

8.1 Is the data store and transmitted (if applicable) securely? ☐ Yes ☐ No ☐ N/A

8.2 Does documentation support that the DSMP is being followed and that safety/data reviews are occurring according to the approved schedule? ☐ Yes ☐ No

DATA MANAGEMENT & SECURITY COMMENTS/ISSUES:

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SUMMARY OF COMMENTS AND ADDITIONAL ISSUES:

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