INSTITUTIONAL REVIEW BOARD
THE UNIVERSITY OF UTAH
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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: