

## AUDIT WORKSHEET 2

Auditor:		Date:		IRB#	
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# SITE OPERATIONS

1. Documentation of P.I./Co-P.I. involvement in conducting and supervising study: Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2. Responsibilities and tasks delegated to qualified personnel: Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
3. P.I./Co-P.I. directly involved in the ICD process: Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
4. P.I./Co-P.I. or study personnel delegate available by phone 24 hours/day to study participants: Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
5. Process in place to maintain study subject confidentiality: Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
6. All investigators and study personnel completed required research training: Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A