

AUDIT WORKSHEET 7

Auditor:		Date:		IRB#	
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DRUG/DEVICE/TEST ARTICLE ACCOUNTABILITY

1. Records of receipt of drug/device/test articles in study file: Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2. All drugs/devices/test articles secured and stored properly (i.e. temperature log, light protections, etc. as per the IDDF): Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
3. Inventory Log – organized, completed, available: Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
4. Drug/device/test article name, dosage strength, and form type: Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
5. Lot number Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
6. Expiration date: Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
7. Date and quantity dispensed: Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

8. Amount transferred/returned/destroyed: Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
9. Date and quantity returned by study participant: Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
10. Date and quantity returned to sponsor:: Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
11. 24 hour emergency telephone number of Sponsor: (Call and see who answers. Is it still the same as the number listed in the IDDF?) Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
12. Chain of custody per regulations or protocol: Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
13. Drug/device/test article used for protocol purposes only: Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
14. Drug/device/test article manual/package insert information in file: Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A