INSTITUTIONAL REVIEW BOARD
THE UNIVERSITY OF UTAH
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AUDIT WORKSHEET 3

Auditor:		Date:		IRB#	

PROTOCOL COMPLIANCE

1. Inclusion/Exclusion criteria met per IRB approved protocol: ☐ Yes ☐ No ☐ N/A
Comments:

2. Screening, study treatment/procedures, performed per IRB approved protocol: ☐ Yes ☐ No ☐ N/A
Comments:

3. Study administered by IRB authorized personnel only and at approved sites: ☐ Yes ☐ No ☐ N/A
(Look for signatures or notes by personnel not on the list, especially in CRFs)
Comments:

4. Only IRB protocol approved concomitant – treatment or medications administered: ☐ Yes ☐ No ☐ N/A
Comments:

5. Modifications to the study protocol prior to IRB approval or exemption: ☐ Yes ☐ No ☐ N/A
Comments:

6. IRB approved study protocol follow-up procedures performed: ☐ Yes ☐ No ☐ N/A
Comments:

7. Drug, Device or test article administration errors: ☐ Yes ☐ No ☐ N/A
Comments: