INSTITUTIONAL REVIEW BOARD
THE UNIVERSITY OF UTAH
75 South 2000 East Salt Lake City, UT 84112 | 801.581.3655 | IRB@utah.edu

AUDIT WORKSHEET 6

Auditor:		Date:		IRB#	

SAFETY MONITORING

1.All Adverse Events (AE) reported to the IRB sponsor and appropriate regulatory agency within required timeline requirements:

☐ Yes ☐ No ☐ N/A

Comments:

2. Serious Adverse Events (SAE) followed to resolution, return to baseline, completion, or judged acceptable by the IRBs and Principal Investigator: ☐ Yes ☐ No ☐ N/A

Comments:

3. All adverse events recorded in subjects record, source document, and CRF or equivalent:

☐ Yes ☐ No ☐ N/A

Comments:

4. All protocol deviations reported to the IRB, Sponsor and appropriate regulatory agency within required timeline:

☐ Yes ☐ No ☐ N/A

Comments:

5. All Data Safety Monitoring Board (DSMB) reports sent to the IRB: ☐ Yes ☐ No ☐ N/A

Comments:

6. IRB notified of unanticipated problems involving risk to subjects at site: ☐ Yes ☐ No ☐ N/A
Comments:

7. All External SAE, Safety Reports and Med Watch-reports submitted to the IRB within required timeline:
☐ Yes ☐ No ☐ N/A
Comments:

8. Periodic Progress reports sent to the IRB if applicable: ☐ Yes ☐ No ☐ N/A
Comments:

9. IRB approval of any changes in research activity as required by regulations and guidelines: ☐ Yes ☐ No ☐ N/A
Comments:

15. All correspondence (e.g., e-mail, letters) to and from the IRB on file: ☐ Yes ☐ No ☐ N/A
Comments: