

AUDIT WORKSHEET 4

Auditor:		Date:		IRB#	
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INFORMED CONSENT DOCUMENTATION

1. IRB stamped ICD correct current version used and in study file: Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2. ICD in each patients source document/medical record: Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
3. ICD's signed, dated and witnessed: Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
4. Parental permission/authorization document signed, dated and witnessed: Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
5. Assent document signed dated and witnessed: Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
6. Consent process documented in source document/progress notes: Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
7. Consent obtained prior to study procedures/and or screening as applicable: Comments:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A



INSTITUTIONAL REVIEW BOARD

THE UNIVERSITY OF UTAH

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8. Subject or legally authorized representative provided with a copy of the consent document: Yes No N/A

Comments:

9. All additional consent documents signed, dated and witnessed. (e.g., consent to collect/ take/ store, specimens, audio/video images: Yes No N/A

Comments: